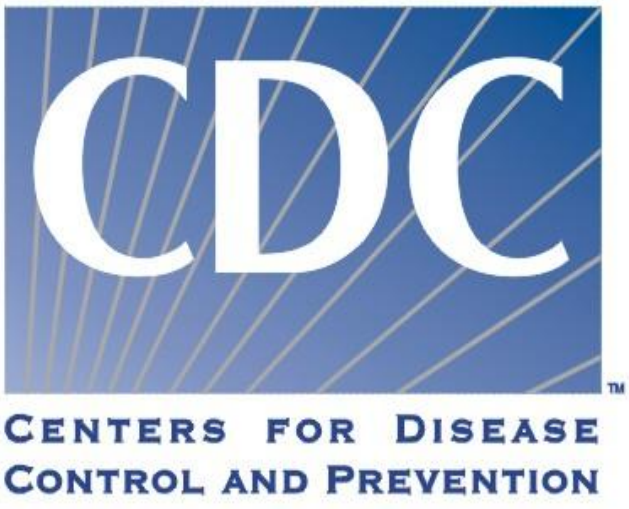
BOARD OF SCIENTIFIC COUNSELORS (BSC)
OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE (OPHPR)
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)



September 14-15, 2011
Atlanta, GA

Record of the Proceedings

AGENDA

Board of Scientific Counselors (BSC)
Office of Public Health Preparedness and Response (OPHPR)
Centers for Disease Control and Prevention (CDC)

September 14-15, 2011

Emory Conference Center Hotel, 1615 Clifton Road, Atlanta, GA 30329
Salon 1-3

Wednesday, September 14

NEW BSC MEMBERS ONLY

8:00 – 8:45 a.m. **New Member Training: FACA, Conflicts of Interest, Ethics**
MASO Federal Advisory Committee Management Staff

8:45 – 9:00 BREAK (15 min)

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ALL PARTICIPANTS

9:00 – 9:20 **Welcome / Individual Introductions / Opening Remarks**
Barbara Ellis, PhD, Designated Federal Official, Associate Director for Science, OPHPR
Thomas Inglesby, MD, Chair, OPHPR BSC
RADM Ali S. Khan, MD, MPH, Director, OPHPR
Dan Sosin, MD, MPH, Deputy Director and Chief Medical Officer, OPHPR

9:20 – 9:35 **OPHPR Organizational Overview and Strategic Planning Update**
RADM Ali S. Khan, MD, MPH, Director, OPHPR

9:35 – 9:50 **Review of FACA Conflict of Interest Issues and Updates on Board Membership**
Barbara Ellis, PhD, Associate Director for Science, OPHPR

9:50 – 10:05 **Discussion of Summary Determinations Process for Peer Reviews**
Barbara Ellis, PhD, Associate Director for Science, OPHPR

10:05 – 10:20 BREAK (15 min)

10:20 – 10:50 **Annual Update on Fiscal Allocation Process Review**
Bill Digioia, MBA, Director, Financial Resources Office, OPHPR

10:50 – 11:10 **Questions and Discussion**
Thomas Inglesby, MD, Chair, OPHPR BSC

11:10 – 11:30 **Vote on Summary Determinations**
Thomas Inglesby, MD, Chair, OPHPR BSC

11:30 – 12:30 p.m. LUNCH (1 hour)

12:30 – 1:00 **Program Response to BSC Recommendations from the Division of State and Local Readiness (DSLR) External Peer Review**
Christa Singleton, MD, MPH, Associate Director for Science, DSLR, OPHPR

1:00 – 1:30	**Questions and Discussion** Thomas Inglesby, MD, Chair, OPHPR BSC
1:30 –1:45	**Vote on Summary Determinations** Thomas Inglesby, MD, Chair, OPHPR BSC
1:45 – 1:55	BREAK (10 min)
1:55 – 2:25	**Program Response to BSC Recommendations from the Division of Emergency Operations (DEO) External Peer Review** Mark Wooster, PhD, Associate Director for Science, DEO, OPHPR
2:25 – 2:50	**Questions and Discussion** Thomas Inglesby, MD, Chair, OPHPR BSC
2:50 – 3:05	**Vote on Summary Determinations** Thomas Inglesby, MD, Chair, OPHPR BSC
3:05 – 3:20	**Vote on DEO Recommendations (#46-48) Tabled at April 22, 2011 Meeting** Thomas Inglesby, MD, Chair, OPHPR BSC
3:20 – 3:30	BREAK (10 min)
3:30 – 4:00	**Report to BSC on External Peer Review of Career Epidemiology Field Officer Program (CEFO)** Herminia Palacio, MD, MPH, OPHPR BSC; Co-Chair, CEFO Review Workgroup John R. Lumpkin, MD, MPH, OPHPR BSC; Co-Chair, CEFO Review Workgroup
4:00 – 4:30	**Discussion and Recommendations** Thomas Inglesby, MD, Chair, OPHPR BSC
4:30 – 4:50	**Vote on Recommendations** Thomas Inglesby, MD, Chair, OPHPR BSC
4:50 – 5:00	**Public Comment Period** (Day 1)
5:00 p.m.	**Adjourn** (Day 1)
6:30 p.m.	*Optional Dinner for BSC members, Ex Officios, and Liaisons (le Giverny restaurant)*

Thursday, September 15

8:00 – 8:05 a.m.	**Welcome – Meeting Convenes for Day 2** Thomas Inglesby, MD, Chair, OPHPR BSC
8:05 – 8:45	**BSC Peer Review Topics for FY2012 / Calendar of BSC Meetings** Barbara Ellis, PhD, Associate Director for Science, OPHPR
8:45 – 9:15	**Report to BSC on External Peer Review of Division of Strategic National Stockpile (DSNS)** Jack Muckstadt, PhD, OPHPR BSC; Co-Chair, DSNS Panel
9:15 – 9:45	**Discussion and Recommendations** Thomas Inglesby, MD, Chair, OPHPR BSC

9:45 – 10:00	**Vote on Recommendations** Thomas Inglesby, MD, Chair, OPHPR BSC
10:00 – 10:15	BREAK (15 min)
10:15 – 11:15	"**Ask-the-Board" Session** RADM Ali S. Khan, MD, MPH, Director, OPHPR
11:15 – 12:15 p.m.	**Updates from Liaison Representatives** (10 min each) • Association of Public Health Laboratories (APHL) • Association of Schools of Public Health (ASPH) • Association of State and Territorial Health Officials (ASTHO) • Council of State and Territorial Epidemiologists (CSTE) • National Association of County & City Health Officials (NACCHO) • National Indian Health Board (NIHB)
12:15 – 1:15	LUNCH (1 hour)
1:15 – 1:45	**Program Response to BSC Recommendations for the Division of Select Agents and Toxins (DSAT) External Peer Review** Rob Weyant, PhD, Director, DSAT, OPHPR
1:45 – 2:30	**Discussion and Recommendations** Thomas Inglesby, MD, Chair, OPHPR BSC
2:30– 2:45	**Vote on Summary Determinations** Thomas Inglesby, MD, Chair, OPHPR BSC
2:45 – 3:00	**Closing Remarks (Action Items and Future Agenda)** Thomas Inglesby, MD, Chair, OPHPR BSC RADM Ali S. Khan, MD, MPH, Director, OPHPR Barbara Ellis, PhD, Designated Federal Official, Associate Director for Science, OPHPR
3:00 – 3:15	**Public Comment Period** (Day 2)
3:15 p.m.	**Adjourn**

Wednesday, September 14, 2011

Welcome / Individual Introductions / Opening Remarks

Barbara A. Ellis, PhD, Designated Federal Official for the Office of Public Health Preparedness and Response (OPHPR) Board of Scientific Counselors (BSC), Associate Director for Science, OPHPR

I am very pleased and excited to welcome our new members as well as current members, liaison representatives and Ex Officio members. We have quorum and therefore are able to convene.

I would first like to review the functions of the Board. The role of the BSC is to:

- Advise the Secretary of Health and Human Services, the CDC Director, and the OPHPR Director concerning strategies and goals for preparedness programs and research
- Administer and over see peer review of OPHPR scientific programs
- May perform secondary reviews of research grants
- Monitor OPHPR's overall strategic direction and focus

We will now have opening remarks by Dr. Thomas Inglesby, Dr. Ali Khan, and Dr. Dan Sosin.

Thomas Inglesby, MD, Chair, OPHPR BSC

Thank you for the honor of chairing this committee. OPHPR is crucial to the nation's preparedness. We are here to identify meaningful, actionable recommendations that can be implemented by the program, evaluate the quality of CDC science, enhance accountability and transparency, and enhance CDC program's focus on the agency's priorities and maximum impact on public health.

Board Members present today include:

- Thomas Inglesby, MD
- Donald Burke, MD
- Sharona Hoffman, JD
- John Lumpkin, MD, MPH
- Ellen MacKenzie, PhD
- John Muckstadt, PhD
- Herminia Palacio, MD, MPH
- Louis Rowitz, PhD
- Elaine Vaughan, PhD (By Phone)

Ex Officio Members:

- Michael Butel, DVM, MPH
- Sally Phillips, RN, PhD (alternate to Alexander Garza, MD, MPH)

Liaison Representatives:

- Mary Gilchrist, PhD
- Damon Arnold, MD, MPH
- Patricia Quinlisk, MD, MPH
- Karen Smith, MD, MPH

No board members had conflicts of interest to declare.

RADM Ali S. Khan, MD, MPH, Director, OPHPR

It is a pleasure to be here. I thank you for taking two days of your time to make sure we do science right.

Thank you to Dr. Ellis and her team for all their hard work. Welcome to our new members and new liaison members. I look forward to a very productive meeting.

Dan Sosin, MD, MPH, Deputy Director and Chief Medical Officer, OPHPR

I thank you also as well. We have two years worth of work to deliberate on for these next two days. We want you to be a part of our process, celebrate our milestones and help us work through our dysfunctions.

I also want to offer a special thanks to Dr. Barbara Ellis. Dr. Ellis will be leaving OPHPR for a new position with CDC. We will miss her greatly, but we have received her gifts for about six years and it plays out in this committee. This Board is the passion, drive, and hard work of Dr. Ellis. It takes a lot of work to push this through. I had the intention of presenting Barbara with a plaque or certificate. We want you to sign this certificate of appreciation before leaving. She's driven by the ability to have good science. Thank you all for being here and thank you Barbara for six years of work.

Barbara Ellis, PhD, Associate Director for Science, OPHPR

I will greatly miss OPHPR and have greatly enjoyed working with all of the board members.

OPHPR Organizational Overview and Strategic Planning Update

RADM Ali S. Khan, MD, MPH, Director, OPHPR

Public health preparedness is the capability of the public health system, communities and individuals to prevent, protect against, quickly respond to, and recover from health emergencies. We have spent the last year thinking about what preparedness really means. I have been involved in bio-terrorism responses, and so therefore it has afforded me some new perspectives. Our job is not about the next contagion or next threat but the everyday preparedness of our nation.

Last Thursday, I hosted the "Contagion" movie premier. I tell people this is about manmade or natural, foreign or domestic, and immediate or distant threats. That it is as much about public health as it is about waiting for the next big event.

I directly report to our CDC Director, Dr. Thomas Frieden. At his heart, he is a local public health person. He has worked with the bread and butter of public health, and that is his passion. Our key role is to support state and local health departments, and that is his main focus.

Within OPHPR, Dan Sosin is our Deputy Director and Chief Medical Officer. Lynn Austin is also Deputy Director and works on the management side of the house.

OPHPR encompasses several divisions. The Division of State and Local Readiness (DSLR), through the Public Health Emergency Preparedness (PHEP) Grant, provides guidance and funding to 62 state, local, and territorial public health departments to strengthen preparedness. They also provide technical assistance and consultation through project officers and CDC subject matter experts (SMEs).

The Division of Strategic National Stockpile (DSNS) operates and maintains the national repository of critical medical assets including antibiotics, antiviral drugs, antitoxins, other life-support medications, and supplies. They also procure, store, and deliver these assets to the site of a public health emergency.

The Division of Emergency Operations (DEO) is a 24-hour center. The Emergency Operations Center (EOC) functions as CDC's command center for coordinating emergency responses to domestic and international public health threats. They are responsible for the overall coordination of CDC's preparedness, assessment, response, recovery, and evaluation prior to and during a public health emergency. They have been activated almost continuously for two year.

The Division of Select Agents and Toxin (DSAT) regulates all entities that possess, use, or transfer biological agents or toxins that could pose a severe threat to public health and safety. They are designed to ensure compliance with the select agent regulations by providing guidance to registered entities and conducting evaluations and inspections. The Division also collaborates with the U.S. Department of Agriculture and the Department of Justice to protect public health by ensuring laboratory biosafety and security among facilities working with select agents.

There was a small investment in 1999 for public health preparedness. At that time we had no stockpiles, and no laboratory response network. We spent a lot of money making sure that local health departments had computers, fax machines, and internet to be able to connect to us. Since that time, much has been accomplished, but much more remains to be done as we continue to enhance and expand public health preparedness.

I do not have to belabor some of our challenges with our current economic crisis. It makes it increasingly difficult to sustain commitments at the federal, state, and local levels and to maintain and build on accomplishments. Currently 38% of the budget goes to Strategic National Stockpile (SNS), 25% to CDC-wide preparedness and response activities, and 34% to the Public Health Emergency Preparedness Cooperative Agreement.

In 2005, we provided almost $1 billion dollars to state and local health departments. Now the budget is reduced to $651,048,000. Academic Preparedness and Response Research centers will be eliminated in the 2012 budget. CDC intramural funding is now at $146,570,000 from $236,909,000 in 2005. So we need to make sure that with these limited funds we accomplish our goals. We need to determine what events we can afford to be prepared for and those we have to let go for now.

Our National Strategic Plan will address some of our gaps and some of you in this room have helped us put together this plan of how to work with state and local health departments. The plan was developed to strengthen and support health security, to save lives, and protect against public health threats. In addition, 8 initiatives were identified to better align with national strategies for preparedness and response that will help measure our accountability and performance.

There are also some new innovations such as the Anthrax Management team, SNS innovations, new warehouses, and revisions made to the select agent list.

We need help from you in getting strategic advice on:

- Setting priorities for CDC public health preparedness
- Maintaining and enhancing public health preparedness at state and local levels
- Developing a strong national biosurveillance capacity
- Strengthening biosecurity and biosafety
- Implementing biosecurity and medical countermeasure Executive Orders
- Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization
- New 5-year Public Health Emergency Preparedness cooperative agreement

Discussion

J. Lumpkin: Has the office worked with the Public Health Accreditation Board on their standards?

A. Khan: Very much so and we are in synch with them.

D. Burke: Can you estimate how much of the budget is going to scientific innovation?

D. Sosin: We will have a more thorough budget brief to go into more detail but there is a substantial amount to ensure that we have subject matter experts (SMEs). We still need more intramural research.

Review of FACA Conflict of Interest Issues and Updates on Board Membership

Barbara Ellis, PhD, Associate Director for Science, OPHPR

I will review our process for external peer review as a refresher for current members and an introduction for new members. I would also like to talk to you about a new process that we have put into place regarding the voting procedure for recommendations.

CDC policy mandates that all scientific programs (including research and non-research) at CDC are subject to external peer-review at least once every five years. CDC policy will likely be changing and more increased flexibility given to Center Director's regarding time period for reviews. There is also a commitment to the intent to increase application of science and science-based principles into OPHPR practices and requirements for external peer review. There is support at the most senior levels to provide these reviews.

Goals of external peer review include:

- Identify meaningful, actionable recommendations that can be implemented by the program
- Evaluate the quality of CDC science
- Enhance accountability and transparency
- Enhance CDC program's focus on the agency's priorities and maximum impact on public health

The scope of the review can include single or multiple activities, a portfolio of organizational units or crosscutting topics, and multiple organizational units at CDC. Depending on the program or topic, a review can be narrow and focused, or broad.

There are other mechanisms for program reviews such as subcommittee reviews, workgroup reviews or external review groups. It was felt by the OPHPR BSC in 2008 that an ad hoc BSC workgroup method was best. This type of workgroup is not subject to the requirements of the Federal Advisory Committee Act (FACA). They are convened to gather information, conduct research, draft a report, and analyze relevant issues and facts. These types of workgroups also do not make decisions. The recommendations are made to the full board and the report is the product of the BSC.

The duration of a BSC workgroup is less than one year and contains at least two members of the Board serving as chair and co-chair. The remaining members are nominated by OPHPR and are recruited based on the expertise that is specifically germane to the topic of the review.

Generally OPHPR convenes pre-meeting webinars to orient the workgroup members to the topic or program of the review. The workgroups meet for 2.5-4 days and draft a report before leaving at the end of their in-person meeting in Atlanta. The BSC co-chairs finalize the report and the full BSC then deliberates on the findings and votes on final recommendations to the Director, OPHPR. At the next in-person BSC meeting, the program provides a formal response to the recommendations and the BSC votes on the adequacy of those responses. Annually, the program office will report to the BSC on the implementation of recommendations until the BSC votes that all recommendations are adequately addressed.

The Science Office tracks the implementation of program recommendations. OPHPR is required by law to report progress on implementation of recommendations from the BSC to the General Services Administration (GSA). What is new is that we would now like to add the step whereby the BSC determines if the program has adequately addressed the recommendations. These determinations will provide an objective and transparent means to evaluate program performance and accountability with respect to the recommendations made by the BSC.

Programs will indicate if they concur, concur in principle (generally due to lack of availability of resources), or non-concur with recommendations made by the BSC and in the case of those recommendations where they concur, they will describe the specific initiatives they plan to undertake to address the recommendations, as well as provide a mini-project plan with milestones and timelines for completion. The BSC will determine if the reasoning for programmatic non-concurrence is adequate and sufficient. For non-actionable recommendations (those requiring resources currently unavailable), the BSC will determine if the program response is adequate should funds become available. We want you to be very critical regarding how OPHPR responds to the recommendations made to us. Let us open this up for discussion.

Discussion of Summary Determinations Process for Peer Reviews

Barbara Ellis, PhD, Associate Director for Science, OPHPR

D. Burke: How many other federal advisory groups are working under CDC, and do they work similarly?

B. Ellis: In 2006, Dr. Gerberding required us to have external peer reviews.

C. Rice: CDC has 23 advisory committees; a few are being terminated and some have been added, like the World Trade Center Committee. We have about four Boards of Scientific Counselors, and their purpose is similar in regards to peer reviews and secondary activities.

B. Ellis: In 2007, the CDC Office of the Associate Director for Science provided guidance to the CDC offices and National Centers on external peer reviews. In OPHPR, we adapted the process of having the BSC vote on the recommendations as something new. I do not know if other BSC's have the same or different procedures. CDC leaves the specifics on processes of external peer review flexible, and to the discretion of the Designated Federal Official with approval from the CIO Director.

S. Hoffman: When I chaired we worked very closely with the program so we could get feedback and my understanding is that we may not have a lot of concurrence. We use the report to work through that. Can you address that?

B. Ellis: The Science Office is like the firewall between the program and the review, so this allows you to make recommendations that may not necessarily be popular with the programs.

D. Sosin: And conditions change. Some things we would have like to have done cannot be done anymore.

J. Lumpkin: I am going to make this suggestion. Having looked at the website for the Board of Scientific Counselors, it does not list the minutes. The assessment by this board would be hard to find. If you could find those minutes and subsequent responses, someone could use those to better inform the government.

D. Burke: A good bit of what I reviewed was operations, management, and more advisory and organizational, so that is why I was wondering if other groups also had the same charge.

D. Sosin: There is no other group on this same subject.

B. Ellis: As stated before, in this meeting we are addressing two years of work that has been done. There have been seven reviews since February, 2009. All but one (DSAT) was done by ad hoc BSC workgroups. There have been lengthy delays on deliberation and voting on workgroup reports and reports to the BSC from programs due to our inability to convene BSC meeting because of quorum challenges. Given the delays, some recommendations may be "overtaken" by events due to changes in OPHPR, Executive Orders, or changes from HHS/ASPR. Programs have embraced most recommendations and developed (in many cases completed) initiatives to address the recommendations made by the BSC.

Annual Update on Fiscal Allocation Process Review

Prepared by Bill Digioia, MBA, Director, Financial Resources Office, OPHPR
Presented by Roberto Garza, MPA, MA, Performance Management and Evaluation Team Lead, Financial Resources Office, OPHPR

The Fiscal Allocation Process (FAP) is OPHPR's process to allocate Public Health Preparedness and Response (PHPR) funding across the agency. The process involves six stages.

- Stage 1: pre-planning and priority setting
- Stage 2: funding guidance and call for proposals
- Stage 3: primary review process
- Stage 4: secondary review and selection process
- Stage 5: communication of results
- Stage 6: performance measurement and evaluation

On February 25-27, 2009, an ad hoc BSC workgroup met to review the current state of OPHPR's FAP, assess the transparency, reliability, and accountability of the FAP, and develop and share recommendations to improve the FAP. From the review, four sets of issues were identified:

- Strategic planning

- Management
- Submission and review of proposals
- Evaluation, lessons learned, and feedback

The BSC approved 14 recommendations that fall within the four sets of issues. Three of the 14 recommendations provided by the BSC resulted in similar implementations and were consolidated into one response.

The first two recommendations addressed strategic planning. Recommendation 1 said that the FAP should be informed at the beginning of the FAP process by input from leaders or managers who have access to and knowledge of the threat assessment. We concurred with the recommendation. To address the recommendation, the FAP is reviewed multiple times each fiscal year by the OPHPR Director and members of his senior staff. These leaders have access to and knowledge of threat assessments, which they introduce into the priority-setting process of the FAP. We believe that we have addressed this recommendation.

Recommendation 2 asked that the FAP should be informed by well-established foresight techniques that include a broad environmental scan of the horizon (social, economic, environment, and technological changes in the broader world) and envisioning new scenarios. In principle, FRO agrees this is a very good idea. However the current budgetary cuts have made it extremely difficult to request and fund an FTE to conduct the proposed work. Therefore the status of this recommendation is has not been initiated because FRO did not receive an FTE to conduct the proposed work.

Recommendations 3, 4, 5, 6, 10, and 12 were all in regards to management. Recommendation 3 asked that we seek more input and collaboration with outsiders in order to generate more ideas. We concurred, and to meet this recommendation, OPHPR leadership is currently engaged in multiple collaborative efforts with a number of public health and preparedness partners across the federal government. These engagements allow OPHPR leadership to leverage input into generating original ideas for the FAP. We believe this recommendation has been addressed.

Recommendation 4 indicated that OPHPR's Chief Management Officer should undertake steps to begin to link costs, budgets and performance information, so that leadership has information about the costs, benefits, risks and redundancies of the investment choices. We concurred and OPHPR leadership tasked FRO to perform a full portfolio management review of all funded activities with the goal of determining gaps and overlaps across CDC in preparedness and response projects and activities. This review linked project costs and performance across different preparedness categories. Furthermore, the Performance Management and Evaluation process tracks performance of all funded activities twice per fiscal year. We feel that this recommendation has been addressed.

Recommendation 5 specified that to what extent there is flexibility, take advantage of it, and encourage partnerships with other parts of CDC to support innovative projects. We concurred and OPHPR routinely encourages CDC CIOs to collaborate in the development and execution of innovative projects. For example, at least three proposals submitted for funding for FY2012 were collaborations between two CIOs. We consider this recommendation addressed.

Recommendations 6, 10, and 12 asked that we:

- Strengthen capacity to measure operations and projects using internal and external experts (6)
- Engage external subject matter experts to serve as peer reviewers (10)
- Create mechanisms for an independent peer review process for on-going programs (12)

We concurred in principle with these recommendations because FRO's budget is not currently funded at a level to include travel expenses for external experts to participate in discussions. As a result we are unable to address these recommendations due to budget constraints.

Recommendations 7, 8, 9, and 11 addressed submission and review of proposals. Recommendation 7 indicated that while some ongoing activities must be funded, review all others more critically. We concurred with the recommendation. We separated the on-going activities into two categories:

- On-going "must fund" activities
- "All other" non-required ongoing activities

We then evaluate all on-going activities twice a year. Those activities that do not achieve 100% of their milestones are reported to OPHPR leadership and their performance is considered when funding levels are set for the next fiscal year. Prior to these recommendations we did not have these evaluation processes in place. We believe we have addressed this recommendation.

Recommendation 8 suggested that we initially call for three-page concept papers then select the top ten choices, requiring only those to submit a full proposal and peer review with external experts. We concurred in principle. FRO implemented the recommendation during the FY2010 call for proposals. None of the CIOs accepted this idea. Feedback received across the agency indicated that activity leads preferred to write full proposals only once. We consider this recommendation addressed.

Recommendation 9 asked that we tailor HealthImpact.net (HI.net) to fit all of OPHPR's needs. We concurred with the recommendation. HI.net as a CDC enterprise system is being retired by CDC/OD. As a result, OPHPR will be establishing an OPHPR-funded program management tool, to be called the Preparedness and Response Investment SharePoint Module, or PRISM. PRISM will be tailored to satisfy the specific requirements of the FAP. Milestones related to this recommendation include:

- Develop PRISM SharePoint Module
- Implement PRISM SharePoint Module for the FY2012 FAP process

This recommendation is in progress with an estimated completion of Spring, 2012.

Recommendation 11 suggested institutionalizing the link between one year's FAP and the next year's planning and budget formulation process. We concurred with the recommendation. The budget formulation responsibilities are presently carried out by the Office of Policy, Planning, and Evaluation (OPPE). FRO will continue to systematically share information gathered during the FAP with OPPE. We believe that this recommendation has been addressed.

The remaining recommendations addressed evaluation, lessons learned, and feedback. Recommendation 13 was to discontinue funding for under-performing projects and shift funding to priority projects that are meeting accepted, agency-wide standards. We concurred and all PHPR-funded activities are performing at the agency-wide standard. Activities that are considered to be under-performing are now required to meet with the Associate Director for Financial Resources to discuss issues and barriers. The OPHPR Senior Advisor for Laboratory Preparedness has performed an initial evaluation of OPHPR-funded laboratory projects and provided a preliminary report to leadership. We believe that this recommendation has been addressed.

Lastly, Recommendation 14 suggested shifting to a two-year FAP and adjust the process every two years, or keep annual FAP and adjust guidelines and processes for proposal submissions and review every two years. We concurred that the FAP should be an annual process but reviewed yearly due to changing landscape. Since FY2011, FRO has reduced the number of new proposals

seeking funding; CIOs are allowed to submit limited number of proposals commensurate with each CIO's engagement in preparedness activities. The two-year FAP has returned to a one-year cycle for two reasons:

- The ever-changing preparedness landscape requires OPHPR leadership to retain the ability to change funding priorities on a yearly basis.
- New funding opportunities are now drafted with a very narrow focus that directly addresses specific outstanding preparedness needs.

We consider this recommendation has been addressed.

Questions and Discussion

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: What we will do now is take questions from the Board.

S. Hoffman: I cannot get a sense of what actual changes were made. I am trying to determine the efficacy. Can you list the significant changes?

R. Garza: Our first change was not to look at things project-by-project but to categorize them and figure out gaps and overlap in funding.

S. Hoffman: So the only change you made was looking at the bigger picture?

D. Sosin: The strategic planning ones, the process described was a bubble-up process. Previously priorities were set by CDC staff. A change was made to adapt the prioritization process such that leadership now decides the funding priorities.

T. Inglesby: So the presentation says that you believe you addressed what was recommended. But was the workgroup useful to you?

B. Ellis: What did not come across were the actual milestones and initiatives. For instance in the case of recommendation 5, prior to the workgroup that was not necessarily called out in the process and it now is.

T. Inglesby: Maybe for future responses to the workgroup, we can say this recommendation was in response to blank, and that will illustrate what the efficacy of the recommendations was.

L. Rowitz: I have a general comment that relates to something I did not hear and that is the assumption that you need a face-to-face meeting to accomplish some of these things. Face-to-face is great, but with funding cutbacks, other alternatives should also be examined. There are times when there is no choice but to have those meetings, but I see several here that could be done through technology.

D. Burke: It is also useful to have a metric. And then the question becomes how you measure responses. I am not sure I can actually give a suggestion there. Are metrics a part of your process?

B. Ellis: It has been with some of the other reviews. Dr. Lindsey provided the first program response to this review, which we did not share because we did not want to cause confusion. In terms of metrics, it is challenges sometimes to

determine what is good enough and what is not and illustrate those through metrics. So we would like your recommendation on that as well.

H. Palacio: There may be other evidence-based reports that could be incorporated in Recommendation 2. Also related to the strategic issues addressed in Recommendation 1, there was a little bit of ambiguity. Did we talk to people who know these things in an explicit manner? I cannot tell that from the written report.

T. Inglesby: So going forward draw out a deeper description of what you have been doing with a particular recommendation.

D. Sosin: If you feel that something more needs to be put into place, to make this more systematic, that is something we want to hear.

J. Lumpkin: This is a new process for me. I do not think OPHPR may concur with the recommendations, and if not, it is fine to say so and give an explanation as to why.

M. Butel: I need more information on Recommendation 2. What level of depth is needed?

S. Hoffman: I do not think they had a specific level but that it is needed.

D. Sosin: I think we are addressing these through the portfolio reviews and looking at what is coming and what do we need to be careful about.

T. Inglesby: Can you give us some clarification. In the coming year, when do requirements get sets, and who sets them? Is it an elaborate process across CDC?

R. Garza: Preplanning starts in November to review the current priorities, how well they are addressed, and see what is missing. Between November to January those priorities are set. Funding guidance is produced between February and March to explain the mechanics to our partners at CDC. It is released in early May to late April. Early May is the call for proposals, and they have until early July to have those proposals submitted. We have one-page proposals within OPHPR, and do an internal peer review and address gaps. We gather those proposals and with the help of the SMEs, each proposal is reviewed twice and scored. We then gather the SMEs in one room for a two-day deliberation to score each proposal, and it does not require consensus. This year we had 30 proposals.

T. Inglesby: How much is at stake?

R. Garza: It changes.

D. Sosin: It is $3.4 million for 2012. Of the full budget, 25% is used intramurally. There is not a lot of discretionary money available for other projects.

J. Muckstadt: How much is the cost to prepare the proposal?

D. Sosin: Not much. These are not long proposals. They are reprocessing proposals that are trying to get funded.

D. Arnold: With all the fiscal issues, is that used to stabilize programs that exist and strengthen them?

D. Sosin: It is a struggle to keep our hands off of that money, so it is probably easier to use those for stabilizing current programs. It is critical for us to bring new ideas and new innovations, so we do have to do that as well. We have changed so much, and what is core and discretionary has changed over time. The first order of business is to pay the bills and salaries for the programs.

A. Khan: So we have 12 to 15 million dollars that has to be used to maintain activities, but a lot of the dollars are tied up in ongoing projects. The total pot for innovation is the 12 to 15 million.

T. Inglesby: So what we are seeing is we have a lot of interest in the budget. Another recommendation was to discontinue funding for programs that were under performing. Can you give more information regarding that?

R. Garza: There was some training for preparedness for environmental health. They were not delivering their training products as promised, so it was stopped.

D. Arnold: We have also started to look at these 5 pillars of funds and whether you have innovative products going out that generate revenue to the Center. I can see where you have a lot of value and can reach out to generate more profits.

D. Sosin: Recommendation 3 does address some of that. We have not done specific fund raising.

T. Inglesby: For Recommendation 4 can you say what you learned in that review? Were there any surprises?

R. Garza: Some of the findings were delivered to Dr. Sosin.

D. Sosin: I am still trying to hire some of the people to do the laboratory preparedness. There are 14 projects that we support that are laboratory related. There are no specific lessons, but it helps to move toward what the workgroup defined, which is to set strategic priorities.

E. Vaughan: I had a couple of questions and I am not sure what the standard is when you say that the status of a recommendation is addressed. For Recommendation 8 there are some problems with this model, but it is a beneficial model to cut down on individual proposals that may not be funded. So when it is addressed, I think one try at this may not be enough. Are there plans to follow up on this?

R. Garza: We can implement this again so we can start informing the national centers to the idea that this is something that is coming again.

E. Vaughan: I am glad to hear that because this model can work very well in the long run. Also in regards to Recommendation 13, I was not sure if this was addressed completely. It does not seem that FRO completely concurred. I heard for under-performing projects they would meet with the program to address barriers and that this would be more of a facilitated role.

T. Inglesby: Dan Sosin did give some feedback on that one and some programs that have been discontinued.

E. Vaughan: Okay. Well thank you for that.

Vote on Summary Determinations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: So we need to figure out what comes off the table and what needs further work.

B. Ellis: If the BSC votes that it has been adequately addressed.

S. Hoffman: What if we want to monitor them.

B. Ellis: Then we need you to make a recommendation that you would like to have an annual update from the program. The most critical thing is if there are things you do not feel are adequately addressed than vote as such and annually the program will come back to report to you on those.

S. Hoffman: So basically if they are doing a good job now, we can say it is addressed and do not have to come back to that.

D. Sosin: I would suggest that you get old business behind us first before moving to new business.

T. Inglesby: So if you wanted to hear some follow up, it can be suggested.

D. Burke: This is somewhat uncomfortable for me but I am not really sure I know what has been done. I tried to do my homework, but I do not think I saw anything about what the money went to. It seems abstract to talk about a process with that in mind.

B. Ellis: We can and have committed to provide you with a briefing. If you feel you do not have enough context to weigh in, then we need to hear that.

D. Sosin: And also this is not a review of the projects.

T. Inglesby: On a personal note, I found looking at the objectives was a better guide as to informing me in that area.

E. Vaughan: I felt the same way. I was expecting something different, but after going through this a second time, I understand it with the objectives we were given. I feel more comfortable now.

T. Inglesby: Are there other things that you do not feel are adequately addressed.

S. Hoffman: I would like to hear about the results on the three-page proposal. We also talked about Recommendation 2. Several board members said they do not need an FTE and that there are other ways to explore electronically or otherwise. I feel we need to hear more about this.

T. Inglesby: John you mentioned on Recommendation 14 you do not feel that they concurred. Do you feel they addressed it?

J. Lumpkin: I feel they addressed it.

D. Burke: On Recommendation 8, I do not know who the 'they' is there that can put in the 3-page proposals. Where is it coming from?

S. Hoffman: We were excited about adopting a system to provide a 3-page paper to show limited efforts in lieu of budget constraints so this is just a change in the process overall.

D. Sosin: And any staff in the Center can apply for these. These are all internal agencies.

A. Khan: Most of our dollars have a fixed cost, but with that part of the budget that is not fixed, then anyone in the agency can apply for those funds. We go through a process to see how to distribute those dollars, and we will give you a list of those projects that were funded.

H. Palacio: Dan, it sounds like you could pull together a brief report on #2. I think we need to be able to say non-concur as John stated because these are high-level reviews from people who may not necessarily understand the fiscal constraints.

T. Inglesby: Can I get a motion to table Recommendations 2 and 8 to ask you to come back and tell us more about the 3-page issue.

S. Hoffman: Second.

T. Inglesby: A motion to vote on the rest of the recommendations?

S. Hoffman: Second.

T. Inglesby: Motion to okay the rest of the recommendations.

Board: Aye [All agree]

[The Board repeated the vote to ensure that they do it correctly.]

T. Inglesby: So the first motion is to table 2 and 8.

S. Hoffman: Second.

T. Inglesby: All in favor?

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

T. Inglesby: The second motion is to approve the remaining recommendations.

S. Hoffman: Second.

T. Inglesby: All in favor?

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

T. Inglesby: Adjourned for lunch.

Program Response to BSC Recommendations from the Division of State and Local Readiness (DSLR) External Peer Review

Christa Singleton, MD, MPH, Associate Director for Science, DSLR, OPHPR

I am representing DSLR and am joined by Christine Kosmos, Eric Carbone and other members of our division. The DSLR review workgroup members were:

- Jack Harrald, PhD (BSC member, Co-chair)
- Ellen MacKenzie, PhD (BSC member, Co-chair)
- Harry Hatry, MS
- Ricardo Millet, PhD
- Patrick Libbey
- Bonnie Arquilla, DO

The purpose of the DSLR workgroup was to:

- Evaluate and provide recommendations to the DSLR process for selecting the Public Health Emergency Preparedness (PHEP) cooperative agreement priority capabilities.
- Evaluate and provide recommendations to DSLR's proposed approach (Change Management Board or CMB) to coordinate, organize, and manage the various CDC, U.S. Health and Human Services (HHS), and partner stakeholders' input in the management of future content for the PHEP funding opportunity announcement.

The workgroup participated in a pre-meeting webinar on August 31, 2009. This pre-meeting permitted for the discussion of DSLR's background materials and allowed the workgroup to ask specific questions regarding the review. On September 15 -17, 2009, the workgroup had its in-person meeting to hear presentations and to participate in discussions and question-answer sessions. The workgroup then conducted their deliberations and produced a draft report. There was a follow-up meeting on October 2009 where the completed draft panel report was submitted. The full OPHPR BSC met on April 26, 2010 (web conference) to vote on the report findings and to present recommendations to OPHPR leadership.

Our first groups of recommendations were in regards to prioritization. Prioritization was addressed in Recommendations 1-6. Recommendation 1 indicated that PHEP funding should be based on 20 targeted capabilities (TC) identified as having central public health relevance. All 37 TC should be listed in the PHEP cooperative agreement; public health capacity created by funding the 20 public health-related targeted capabilities may support one or more of the remaining 17 capabilities. We concurred in principle. Although the capabilities determined to have central public health relevance were determined using the 37 Department of Homeland Security (DHS) Target Capabilities List (TCL) as a baseline, the National Health Security Strategy capabilities were also considered. To include the TCLs in the cooperative agreement "for informational purposes" would have added undue programmatic burden with data collected on topics outside the program's scope.

To address this recommendation, DSLR:

- Engaged CDC subject matter experts to define the scope of the capabilities determined to be of central public health relevance (completed January-December 2010).
- Determined capability definitions, essential tasks, and resource elements (completed January-December 2010).
- Reviewed/vetted capability definitions with internal and external stakeholders (completed September-December 2010).

We were able to bring those target capabilities down to 15 and believe that this recommendation has been addressed.

Recommendation 2, a short form of the TCL, should be provided as a PHEP cooperative agreement appendix. DSLR should be prepared to provide interpretation and clarification of the targeted capabilities. We concurred in principle. To address this recommendation, DSLR determined capability definitions, essential tasks, and resource elements (completed January-December 2010); reviewed/vetted capability definitions with internal and external stakeholders (completed January-December 2010); included capability definitions as components of the 2011-2016 PHEP cooperative agreement guidance (completed April 2011). We feel that this recommendation has been addressed.

Recommendation 3 said that the 20 public health-related targeted capabilities should not be divided into 3 prioritized tiers or rank-ordered. DSLR concurred with the BSC recommendation. However, CDC leadership (Dr. Thomas Frieden) disagreed and requested DSLR prioritize or tier the capabilities into the areas that he believed were the "foundation" for public health.

Tier 1 Capabilities

- Public Health Laboratory Testing
- Public Health Surveillance and Epidemiological Investigation
- Community Preparedness
- Medical Countermeasure Dispensing
- Medical Materiel Management and Distribution
- Responder Safety and Health
- Emergency Operations Coordination
- Emergency Public Information and Warning
- Information Sharing

Tier 2 Capabilities

- Non-Pharmaceutical Intervention
- Medical Surge
- Volunteer Management
- Community Recovery
- Fatality Management
- Mass Care

Language was added to align more closely with the BSC recommendation. It states that "CDC's tiered strategy is designed to place emphasis on the Tier 1 capabilities as these capabilities provide

the foundation for public health preparedness. Awardees are strongly encouraged to build the priority resource elements in the Tier 1 capabilities prior to making significant or comprehensive investments in Tier 2 capabilities."

To address this recommendation, DSLR conducted or will conduct the following:

- Determination of capability definitions, essential tasks, and resource elements (completed January-December 2010).
- Annual receipt/review of awardee progress reports (completed each November between 2012-2017).
- Determination of performance measures for each of the identified capabilities (completed by April 2012 with periodic review thereafter).
- Annual and final project analysis of progress report results and performance measure reports (completed each December between 2012–2017 with final report April 2017).

Once complete, we believe that this recommendation has been addressed.

Recommendation 4, CDC/DSLR efforts to define a limited number of performance and outcome measures for each of the public health prioritized capabilities should be continued and, if possible, accelerated. We concurred in principle. HHS, Assistance Secretary for Health (ASPR) has decided that the PHEP should be aligned to our sister program, the Hospital Preparedness Program (HPP). To address this recommendation, DSLR conducted or will conduct the following:

- Establish a two-year work plan to develop performance measures based on the NHSS and new PHEP cooperative agreement (completed September-November 2010).
- Prioritize capabilities for which performance measures (PMs) will be developed (completed September-November 2010).
- Develop initial performance measures for the 15 capabilities, including at least three joint HPP/PHEP measures:
    - April 2011 initial PHEP performance measure workgroup convened for fatality management, volunteer management, and medical surge
- December 2011: Additional joint HPP/PHEP PMs for fatality management, mass care, medical surge, and volunteer management. These will be developed and released in collaboration with ASPR HPP:
    - April 2012: PMs for remaining PHEP capabilities finalized for information sharing, non-pharmaceutical interventions, and responder safety and health. (Specific timeline for community recovery capability is to be determined).
    - Various piloting and desk reviews will be conducted for all measures. Comprehensiveness of piloting is dependent on timing of completion of measures as well as senior leadership direction.

This recommendation is to be completed by the summer of 2012.

Recommendation 5 said that the PHEP cooperative agreement should require a hazards and vulnerabilities/gap analysis be completed in year 1. Hazard and vulnerabilities/gap analysis should drive a 5-year strategic plan that addresses how the awardee will address the 20 public health related-targeted capabilities. The five-year strategic plan should be viewed as a living document, updated on a regular basis, and used to determine future funding needs. We concurred in principle. To address this recommendation, DSLR conducted or will conduct the following:

- Internal division review of existing awardee jurisdictional risk assessment to determine current environment of awardee planning (will be completed fall 2011).
- Development of sample decision matrices to assist awardee planning (completed March 31, 2011).

- Development of guidance to support the new PHEP framework (5-year strategic forecast, alignment of budget to work plan; completed April 2011).
- Technical assistance strategy and implementation (will be completed January 2012).

When these activities are completed, we believe this recommendation will be addressed.

Recommendation 6 suggested that technical assistance/guidance materials should be provided by CDC, including performing and reporting hazards and vulnerabilities/gap analyses. We concurred in principle. To address this recommendation, DSLR conducted or will conduct the following:

- Internal review of existing awardee public health, medical, and mental/behavioral health risk assessment and strategic plans to determine current environment of awardee planning (will be completed fall 2011).
- Technical assistance strategy implementation (will be completed January 2012).

The expected date of completion is January 2012.

Our next section was the Change Management Board (CMB). Recommendation 7 said that the Chair of the CMB should directly report to the Deputy Director within the Office of State, Tribal, Local, and Territorial Support. We did not concur. DSLR believes the Director of the Office of Public Health Preparedness and Response (OPHPR) is best positioned organizationally to function in this role. The OPHPR Director reports directly to the CDC Director and maintains organizational authority over the DSLR Director. Since this recommendation was provided to OPHPR, we began alignment with the Hospital Preparedness Program. The OPHPR Director and HHS/Assistant Secretary of Preparedness and Response (ASPR) currently provide executive leadership for this White House-directed grant alignment initiative to coordinate the PHEP program and the HHS/ASPR Hospital Preparedness Program (HPP) in the most cost-effective manner possible. The PHEP/HPP grant alignment initiative is currently overseen by a Grant Alignment Board that governs all aspects of the grant alignment initiative and serves as the CMB, approving recommendations for further alignment, approving program changes, and coordinating overall decision making. It is now acting as the CMB. We feel that this recommendation has been addressed.

Recommendations 8, 9, 10, 11, 12, and 13 also pertain to the CMB but are very similar. Recommendation 8 suggested that explicit criteria should be developed to assist in categorizing a proposed change as an administrative revision/update not requiring full review by the CMB. We concurred in principle. To address this recommendation, DSLR will:

- Identify specific procedures for HHS/ASPR and CDC project officers to conduct joint reviews of awardee submissions to manage program changes resulting from the grant alignment initiative.
- Implement HHS/ASPR and CDC-specific procedures for conducting joint awardee application reviews resulting from grant alignment initiative changes.
- Timeline for implementation: May 2012.

We expect completion by summer 2012.

Recommendation 9, explicit criteria should be developed for review of all proposed change requests brought to the CMB. Criteria should include consideration of cost and burden of proposed change on awardees; impact of proposed change on currently funded programs; and the overall feasibility of implementation, including technical and timeliness considerations. Both short and long-term effects should be considered. The criteria suggested by the BSC will be used to assess the achievement of the goal “reduce awardee burden and increase customer satisfaction:” To address this recommendation, DSLR conducted or will conduct the following:

- Identify/confirm additional criteria for reviewing proposed change requests in collaboration with HHS/ASPR.
- Integrate criteria suggested by the BSC into the written change management agreement.

The timeline for implementation is April 2012 and completion is expected in the summer of 2012.

Recommendation 10, requests should be forwarded to NACCHO and ASTHO for their comments on the request and its potential impact on awardees. We concurred in principle. To address this recommendation, DSLR conducted or will conduct the following:

- Coordinate with OGC and PGO to identify options for including ASTHO and NACCHO into the change management process for the new FOA.
- Identify triggers and parameters for including ASTHO and NACCHO within the change management assessment process.
- Coordinate with ASTHO and NACCHO.

Expected time of completion is the spring of 2012.

Recommendation 11 indicated that to ensure timely and consistent review, carefully consider frequency of CMB scheduled meetings to prevent backlog and unnecessary emergency meetings. We concurred and currently the Executive Leadership Team currently meets monthly; Grant Alignment Workgroups currently meet weekly; and the Grant Alignment Board currently meets bi-weekly to review Grant Alignment Workgroup recommendations. To address this recommendation, DSLR conducted or will conduct the following:

- Establish long-term sustainable schedule for Grant Alignment Board activities after awardee funds are released in 2012.

We anticipate completion by the summer of 2012.

Recommendation 12 suggested that all change requests should be resolved within a reasonable, predefined time limit. We concurred. To address this recommendation, DSLR conducted or will conduct the following:

- Develop a mutually agreed upon process for managing a change request originating from an external stakeholder.
- Document the procedure for resolving change requests within the change management agreement in a timely manner.

We expect completion by the summer of 2012.

Recommendation 13 prescribed that an appeal process should be defined to preserve the integrity of the process. We concurred with the recommendation. To address this recommendation, DSLR conducted or will conduct the following:

- Identify designated HHS/ASPR and DSLR points of contact that are to be responsible for managing and coordinating the overall change request process.
- Describe an appeal process within the change management agreement.

We anticipate completion by the summer of 2012.

Recommendation 14, Program Change Request Tracking System should be implemented to manage tracking of change requests, provide more efficiency, and provide clear record of events. The system would automatically: (a) identify who needs to review each category of request (such as whether emergency or not, changes relating to particular hazards, those that are purely administrative change requests, etc.); (b) track status of those reviews and needed approvals for

each category of request; (c) keep track of the time periods and give warnings for behind-schedule reviews; and (d) summarize overall progress of the changes for the year. CDC would likely need to designate a "Program Change Administrator," if only part time. We concurred with the recommendation, and DSLR is currently using a project management approach to track all change requests, risks, dependencies, and recommendations related to the grants alignment initiative. All information is currently shared between DSLR and ASPR using a SharePoint site. To address this recommendation, DSLR conducted or will conduct the following:

- Establish a SharePoint site accessible to HHS/ASPR and CDC Grant Alignment Board members (completed August 2011).
- Employ project management methodologies to track individual workgroup progress with managing changes, risks, dependencies, and recommendations (implemented June 2011).

We believe that this recommendation has been addressed.

Lastly, Recommendation 15 said that after one year of implementation, the process should be internally reviewed and changes made accordingly. We concurred. The final product of the DSLR change management development process will be to document and formalize the change management process; this will be led by the Policy, Guidance, and Communication Workgroup. To address this recommendation, DSLR conducted or will conduct the following:

- Document the change management process.
- Achieve concurrence with the Grant Alignment Board.

A completion date of fall 2012 is expected.

Questions and Discussion

Thomas Inglesby, MD, Chair, OPHPR BSC

E. MacKenzie: I realize that a lot has changed since we initially reviewed this, and I appreciate the responsiveness to the recommendations. Two things I remember that were important were that target capabilities should not be prioritized, but Dr. Frieden disagreed. I agree with the two categories he has set up, but I am still not clear on the CMB and the Grant Alignment Board. Are they becoming one and the same?

C. Singleton: Exactly. Since the programs are becoming aligned these will go through a joint process since changes will also affect the sister program.

E. MacKenzie: We felt very strongly about developing performance measures, and I still get a sense that some of the measures are still in development. To what extent are you holding the grantees to using those performance measures on a year-to-year basis?

C. Singleton: At the time of the meeting, we had about six clusters of performance measures. We developed three more measures. We decided to ramp up four of them to have them all done by early 2012 so that all 15 TCLs would have a performance measure. The sister program will have the same but will be hospital-centric.

E. Carbone: It is clear that the Grant Alignment Program has added some complexity, so we are working closely with them. There will be several joint measures that will be in place, and the target is December 2011. The overall measures are expected to be rolled out by April or May 2012. We recognize that we have got a number of measures looking at processes and performance but we are looking more strategically at how to measure effectiveness and distal outcomes. That is on the table right now.

C. Kosmos: We also realized that we needed a foundation document to direct that work, and having the planning guide that was released in March has helped us to accelerate our efforts.

C. Singleton: Grantees have to do a demonstration plan. They have to show where they are in the capabilities and demonstrate it. We also continue to be resistant to targets that are not backed by evidence.

S. Hoffman: I would like some clarification between the differences of concur and concur. What principal did you have in your mind?

C. Singleton: Concur is we followed the recommendation all the way down. Concur in principal is that we concurred with some of the things but not in its entirety.

J. Lumpkin: What I took away from your presentation is that on Recommendation 3 you now do not concur. I think there was somebody at CDC that did not concur but the issue has been addressed.

C. Singleton: The Division agreed and Dr. Frieden said he did not agree.

J. Lumpkin: We stated before that we do not expect everything to be concurred with, and that is okay. I would urge you that if you cannot get a science base that your non-concurrence suffices.

K. Smith: I have been on the evaluation process for the last four years. The real concern about good enough is the intent to tie budget to this. If you do not meet your metrics you lose funding. We do not even have good methodology for rolling these things out to states. We have had a lot more compromise, and targets are a whole other animal, particularly when you talk about taking things away.

D. Arnold: Once the recommendations are made by this board, do they go back to your combined ASTHO and CDC board?

C. Singleton: You stumped us on that one Damon.

D. Sosin: These are changes to DSLR but not necessarily for the change management process. There is no reason that this has to go through a new or different process to resolve them. If you feel we need to continue to track some of these, we can come back on future meetings and share ongoing information.

T. Inglesby: When you read the workgroup report, I got the idea that the request for change could come from so many places and in so many ways. So who can request a change to the program, and how do you all decide on that?

C. Singleton: Right now anyone can make a request, a stakeholder that is. We typically get consensus around CDC. Prior to the ASPR program, we had a different process. Now with the sister program, we have to step this process through with them for grant alignment in one of our monthly meetings to determine if it complies and what the impact of it will be.

T. Inglesby: So has there been a 5% change in the program? Ten percent?

C. Singleton: We would get annual changes. Some are big changes. If something does not align to the 15 capabilities, we are not likely to add it.

E. MacKenzie: So the change management process has been morphed.

S. Hoffman: It would help to see significant changes made as a result of this review. I think it would be good to ask all programs to show what was done as a result of the review.

J. Lumpkin: Thinking back to performance metrics, it seems as though those are tied to the PHEP. Is there another way that this office can assess state preparedness? There are some things that states do on their own. If the PHEP continues to change, there is no longitudinal metrics.

E. Carbone: There are the issues of process and program measures specific to the PHEP. We have given thought to how we are going to measure effectiveness more broadly through special studies, preparedness index project, etc., so we are trying to broaden the scope. The recognition is that there needs to be broader metrics and we are working on those currently.

A. Khan: We would like to have some longitudinal indices to inform what the impacts are and be able to compare ourselves because we are constantly asked are we prepared enough. There is a lot of effort within OPHPR in regard to this.

J. Lumpkin: I would suggest that this would be a valid topic for discussion and advice.

D. Arnold: I think there is some operational efficiency gained by this type of thinking. Also between CDC and ASPR you have different geopolitical things going on in the background. Do those cause issues with you aligning? How does it affect sustainability?

C. Kosmos: In order to maintain sustainability, it is even more necessary that we bring these two programs into alignment. We found a lot of overlap, and we need to ensure that we are not duplicating one another. We need one planning unit, one administration, etc. It makes sense. This way we do not have resources going everywhere. We are mirroring a lot of what is already happening at the state and local level.

T. Inglesby: Elaine any questions?

E. Vaughan: I did not see in the recommendation anything regarding drills and exercises. I think this is very important to do, and we learned a lot about that from the H1N1 epidemic.

C. Singleton: The workgroup recommended that we consider the output from exercises, but we do not necessarily see it as a performance metric. In our capability document, we have things that they must do and then show us how that will be done. This data will inform outcome measures. We see this right now as a way to better understand.

D. Sosin: Is it possible to put together a one or two pager that will better explain this and Eric will update the group on where we are going and how fast we are going there?

E. Carbone: Sure, I think we can do that right away.

D. Sosin: And when they are completed in the spring or summer, we could get an update on that.

T. Inglesby: With respect to CDC dollars provided to state and local health departments, what proportion comes from the PHEP?

B. Ellis: We can give you that.

A. Khan: It is about 30 to 40% I believe. We have some state representatives that can potentially talk about that.

D. Arnold: For Illinois, 66% of my budget goes to a majority of this. About 59% of that is federal and 41% other areas. The Office of Preparedness and Emergency Response is a relatively small portion of our budget.

K. Smith: One of our challenges is that the PHEP asked for more than what we receive in funds.

Vote on Summary Determinations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: So do we have a motion?

J. Lumpkin: The issues that are addressed we concur and those others we come back and address, so 1, 2, 3, 5, 7 and 14 will be listed as addressed and the remainder will be brought back and completed.

T. Inglesby: Second motion?

J. Muckstadt: Yes.

S. Phillip: Should they do a new program versus piggybacking this on to what was initially developed.

D. Sosin: We can put that on the table, but there are still some things that are not completed and are going to be completed.

D. Burke: So the expectation is the CMB will be functional by next summer. Is that correct?

C. Singleton: The next time the Board meets, we will have an update on the process.

T. Inglesby: So the ones tabled are those that have a completion for next year some time. So we will bring those back. Second the motion?

S. Hoffman: Second.

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

Program Response to BSC Recommendations from the Division of Emergency Operations (DEO) External Peer Review

Mark Wooster, PhD, Associate Director for Science, DEO, OPHPR

I would like to thank Drs. Bob Ursano and Lou Rowitz, co-chairs of the ad hoc BSC workgroup for helping and engaging us in our review. From 2010 to 2011, we were occupied with an unprecedented amount of activities, so we thank Bob and Lou for their work to help us improve our processes during that trying time. A lot of things have changed in these two years. We have seen a cultural change. Our stakeholders are more willing to work with us in the Emergency Operations Center (EOC), and we sometimes have a challenge getting them to leave. But this we see as a positive change.

The objectives of the review was to provide an evaluation of the efficiency and effectiveness of CDC's Emergency Operations Center (EOC) to fulfill its mission to support and coordinate the CDC response to a public health emergency event and make recommendations that may result in improvements to:

- Barriers
- EOC Facilities and Work Environment
- EOC Procedures
- EOC Services
- Feedback Mechanisms
- Training
- Metrics

There was also a review of the Director's Critical Information Requirements (DCIRs) concept, and providing recommendations on the current framework that is used to prioritize actionable information provided to CDC leadership.

The DEO workgroup members included:

- Dr. Louis Rowitz (BSC member, Co-chair)
- Dr. Amy Kircher
- Dr. William Waugh
- Dr. Stephen Ostroff
- Dr. Robert Ursano (BSC member, Co-chair)
- Mr. Phillip Padgett
- Dr. Cheryl Bolstadt

The following timeline was followed:

- Pre-meeting webinar: January 19, 2010
  - Overview presentations on DEO and CDC's response mission, EOC utilization and activation, and Director's Critical Information Requirements (DCIR) concept
- BSC workgroup meeting: January 26-28, 2010
  - 2009 EOC stakeholder survey results
  - Four internal stakeholder focus group panels
    - Emergency Coordinators (ECs), Subject Matter Experts (SMEs), Leaders, OPHPR
  - DEO presentations and document reviews
- BSC deliberation and vote on recommendation from BSC workgroup: April 22, 2011
- DEO's first program response to BSC workgroup recommendations: September 14, 2011

There are 43 recommendations plus 2 and 7 that are subparts to recommendations, so there are a total of 50 discrete recommendations. Of those 50 recommendation, 36 we concurred with and 14 we concurred with in principal.

Recommendations 1-4 addressed barriers. As a result of this review, we established monthly Centers, Institutes, and Offices (CIO) EC meeting, which promotes services, provides an opportunity to obtain feedback, develop stronger interpersonal relationship, build trust, and EC policy. The EC Staffing Network, coordinated by Emergency Personnel Staffing Team (EPST), was initiated during the spring of 2011. Further, in response to these recommendations, we established steering committees to work in an oversight capacity. The Steering Committees are composed of CDC stakeholders. The newly established committees include: the Exercise Steering Committee, Evaluation Steering Committee, and Planning Steering Committee. DEO provides support to CIOs outside of activations. As stated before, in 2009 the EOC was not the popular choice for conducting emergency operations, but today the EOC is the choice.

As recommended, this year we also conducted an EOC and Incident Management System stakeholder survey and are currently looking at these results. After Action Reviews (AARs) are now used to post responses and obtain feedback on how we are doing. Newly developed EOC training courses are available to all CDC staff, and the newly established Process Action Team (PAT) is used to determine when a centralized management of a response is appropriate. It is comprised of representatives from:

- Lead technical programs supporting the response
- Other technical public health programs engaged in the response activities
- OPHPR and DEO Leadership

The next category was Facilities and Environment. Recommendations 5-12 addressed those. To attend to those recommendations, the following accomplishments have been made:

- CDC EOC facility has more capabilities than most EOCs
  - Enforcement of the 8 hours work shift and 2 week rotation

    - Staffing is such that lifestyle concerns related to long hours is now not an issue for most CDC staff working in the EOC since the hour work shift has been instituted
- Additional EOC space
    - Two established Continuity of Operations (COOP) sites
- Reserved parking during responses established
- Pilot testing of a pay-as-you-go option for food completed
- Shower facilities available in the same building as the EOC
- National Institute for Occupational Safety and Health (NIOSH) conducted sound surveys throughout CDC's EOC in 2010.
    - Noise canceling tiles have been installed to reduce noise on the main floor
- CDC's Office of Safety, Health and Environment (OSHE) studies of EOC air quality completed
    - CDC's Building and Facilities Office (BFO) engaged
    - Recommendations made and addressed
    - Problems resolved
- Visits to seven local and state EOCs have allowed for assessment of other EOCs
- Virtual capability
    - DEO's Operations Branch has developed processes and procedures to enhance the ability to work virtually
    - Laptops and other necessary equipment issued
    - Virtual capabilities enhancement cost analysis will be completed when funding is available
    - Regular evaluation of IMS roles that can be carried out remotely
- Homeland Security Information Network (HSIN)
    - Created as a community of interest collaboration platform to exchange lessons learned, best practices, and ideas
    - Includes state and local EOCs

The next area was related to procedures and was addressed in Recommendations 13-17. To address these recommendations the EPST was founded to deal with the EOC "human resource" activity. It was created in June 2010 to manage identification and placement of field and CDC IMS staff; coordinate with key leadership; develop and maintain systems to gather information and report on staffing accountability; and plan and process non-cash awards for service. Event demobilization plans were distributed and defined tour of duties was established. Through this effort, CIO relationships have improved. They now understand the role and value of the EOC. Communication has improved and there is somewhat a reluctance to deactivate.

Services were tackled in Recommendations 18-20. Several accomplishments were seen as a result of the recommendations:

- DEO and OPHPR are active leaders and members of several committees and working groups related to EOC Situational Awareness (SA) Capabilities
- DEO and OPHPR support the development of a Social Networking workgroup
    - Determine if using these tools internally is useful and feasible
- Emergency Operations Management System (EOMS) has been developed as the CDC IMS Virtual Network

The Social Networking workgroup is still an open area. We want to find out what issues can be used to make this feasible.

Recommendations 21-27 addressed improvements to feedback mechanisms. Successes seen as a result of the recommendations were:

- Plans, Training, Exercise and Evaluation (PTEE) Branch conducts Interim Progress Reviews (IPRs) during responses
    - Identifies corrective actions
- Post-response feedback
    - Select individuals involved are debriefed
    - Immediate After Action Review (AAR) (Hot washes)
- OPHPR Evaluation Program Steering Committee
    - Meets monthly to discuss AAR corrective actions
    - CIOs provide representatives
- Semi-annual meetings with ECs and CIO SMEs
    - Discuss CDC EOC issues of concern
    - Held during scheduled EC meeting
- Web-based comment form available
    - Managed by PTEE
- DEO and OPHPR will consider an external EOC stakeholder survey
    - Contingent upon funding
    - In collaboration with representatives from programs
    - Office of Management and Budget Paper Work Reduction Act (OMB-PRA) regulatory requirement needs to be addressed

Recommendations 28-34 addressed training. As a result of those recommendations, now, all DEO staff are trained in CDC IMS requirements. Also, all DEO staff receive regular training related to the EOC. The CDC University's School of Preparedness and Emergency Response provides online courses related to the EOC, and there is a Surge Staff policy in place. The EPST has developed Job Action Sheets and Standard Operating Procedures for IMS roles. OPHPR is working with other federal agencies and the Office of Personnel Management (OPM) to develop a job series specific to emergency management, appropriate career training ladder, and a cross-agency committee to address new job series. There are incentives for EOC service and training such as awards and certificates of participation provided to all individuals filling IMS roles. There is now a basic National Incident Management System (NIMS) training required for all CDC staff to be included in performance reviews.

The metrics category are addressed in Recommendations 35-38. We now have an annual EOC and IMS Stakeholder Survey, and after-action reports. The EPST provides information on EOC utilization routinely during a response on organizational entity, number of responders, and duration. In addition, CDC's Emergency Management Program is seeking assessment and accreditation against DHS recognized national standards by the non-profit Emergency Management Accreditation Program (EMAP). We have received funding to go forward with that effort.

The last category is related to DCIRs and they are addressed in Recommendations 39-45. There were also successes seen in this area:

- DEO examined several approaches to improve communication with the Director
    - Decided on Department of Defense approach
- CIOs provide the EOC with regular updates including:
    - Situational Reports
    - General information
    - Reports on emerging public health issues
    - Potential deployments
    - Other information needed for situational awareness
- DCIRS developed by Operations Section and lead program at beginning of a response
    - Reviewed regularly

Questions and Discussion

Thomas Inglesby, MD, Chair, OPHPR BSC

J. Lumpkin: I keep looking at my spreadsheet, and I only see 48.

M. Wooster: There are 7 subparts.

J. Lumpkin: There are a few that are contingent on funding. I wanted to raise social networking as an issue. I think that would be less of a security issue. If you compartmentalized that and look at what the Army did in that area, it would be helpful. They are using secure methods to do that function. For the after-action reports, you can use things like Survey Monkey, which can be done on the fly to accumulate data, and it is relatively inexpensive. This was a fairly comprehensive approach. Rather than going through all this detail on a regular basis, take those that we have funding for, for 2012, and only come back to those.

M. Butel: Those that are contingent on funding, will we just be leaving those on the books or will we go to others that are more important?

D. Sosin: If we have intent or hope of addressing that, we can do that in a different way. But we are asking for your feedback on that.

T. Inglesby: Recommendation 3, how does this work? Say somebody else in CDC is working on something in Kenya, who pays for it?

M. Wooster: It depends on the situation. We try to do it on our budget.

P. Navin: The UN and our international colleagues are working the dollars. They will say, “here’s our dollars please, assist us,” so there is nothing coming out of our budgets at this time. But if there is not a mission assignment through the state to travel somebody, then we are probably not going to see it.

T. Inglesby: So has it been the case that you could not respond because you did not have the money?

P. Navin: If the need arose, we can go to senior leadership to get the dollars. We would get that from other funds.

T. Inglesby: You said some were hesitant to use the EOC. Why was that?

M. Wooster: Some were unfamiliar with using NIMS, lack of control, difference in cultures. Part of that has been corrected by training but most was lack of training and engagement.

T. Inglesby: Is there cross efficiency now?

P. Navin: Yes, I think people realize that this is a better way to operate. We have many capabilities that they are finding very vital, and its value added.

L. Rowitz: One thing that helped us was Mark working with us on the survey and everybody in the workgroup had a tour of the EOC. We could see what the issues were as we walked through. It helped in our recommendations

P. Navin: Tying programs together through agencies also helps. We are getting closer to our goal, and it brings more people into that field of study.

D. Arnold: With the NIMS system, in 2009, I had them pull the panflu plan off the shelf and it assisted them greatly. It goes back to the question of- is there a certain core amount of information that people should know? I am wondering if there is something that we should be learning from this. If people had that basic understanding in how the system works and where they fit in, then transitioning is not a big burden. As a side note, I would be careful about personnel assignment with union issues.

T. Inglesby: I have a question about debriefs and after-action reviews. How are you able to wrap those back into the program?

D. Kennedy: There is a combination of stakeholder surveys and hot washes, depending on how long the response is. The final written product, or after-action report, gives a summary of recommendations. We have a summary quick look and it captures 5 quick things identified, and then we also have some long-term recommendations. These are examined by Dr. Khan. There is a tool on our common operating picture that has a form that can be filled out as well.

D. Sosin: Those corrective actions are tracked on a quarterly basis so it is an ongoing improvement process.

S. Phillip: I am intrigued about the accreditation process. There are some pluses and minuses such as you must sustain your accreditation, and then there is the cost that goes along with that. Have you done a cost analysis for that?

P. Navin: There was a White House report that said that all EOCs should be accredited, and so we decided to follow that recommendation. This will also help us to get those in our local and state area to reach the accreditation level. This could also be done globally.

M. Wooster: Phil is referring to the September 2010 report that identified issues with identifying metrics. They felt you should go to standards and mentioned the accreditation program. We want to know what is the value added to our programs. When I first took this up with the accreditation folks, there were two other federal agencies that were running through this pilot. We are the third federal agency to engage in this type of process.

A. Khan: So this is a highly unusual process, and I challenged them to set standards. We wanted to determine how prepared we were and how do we measure ourselves. So maybe we can cue that for a robust discussion next time. We can determine a metric for where we are and then determine where we need to go further.

L. Rowitz: The other side of the coin is individual certification. States do have a process where emergency managers can get certifications.

D. Arnold: We have the CEOC and then the state emergency operation center. This can cause an issue in trying to find balance. We always say that public health and faith-based organizations never leave the field. So finding somewhere that that balance works out is important to us.

T. Inglesby: So you want to relate this to the CDC EOC?

D. Arnold: Yes.

T. Inglesby: DCIR, you said you used the DOD approach and Tom Frieden uses that approach. What does that mean?

M. Wooster: This is information that the Director wants brought to their attention. It is a list of issues or events, and we can certainly provide those.

T. Inglesby: That would be helpful.

A. Khan: There are about a dozen of them and they are immediately actionable by the CDC Director. So if a pandemic comes about, we can immediately address it.

M. Wooster: These inform us on what the Director wants and facilitates upward communication.

D. Burke: I do not know whether this list is drawn up on perceived values or if it is a more involved process.

M. Wooster: It is coming from the Department of Defense model. It is what the Director wants to be informed about immediately, 3:00 in the morning type of situations.

D. Sosin: There is a certain amount of trial and error in that as well because Dr. Frieden's list and Dr. Gerberding's list are different.

D. Burke: As you go up higher in the command chain, it might be worth it to formalize the process.

D. Sosin: DCIRs have some nuances. In a particular event, there are things that the Director will ask that are not part of that DCIR list.

T. Inglesby: That might be a discussion for a future meeting to educate the BSC on what the formalized process.

M. Wooster: There are two set of DCIRs. There is the 14 or 15, and then there is the incident-specific ones, and those change. We will give you the standing ones and the ones used during H1N1.

S. Phillip: I know the committee focused a lot on the DCIR process. How much different is it from your normal output? Is there overlap and to what extent?

P. Navin: They can vary with event-specific DCIR.

D. Sosin: The issues the director mainly wants to know is what is on the Situation Report.

T. Inglesby: On question 35, it would be constructive to show how useful and valuable the EOC is, even if it is in a descriptive way, some qualitative way. Right now the budget is stable for that, but for future uses, it may be helpful.

D. Arnold: When we say impact are we talking about short- or long-term financial, or how they impact longitudinally?

M. Wooster: The short-term impact is that we help them do their job better. Long-term metrics are a lot more challenging to come up with.

Vote on Summary Determinations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: Are there any recommendations to table?

J. Lumpkin: I suggest we table 19, 26, 33, 34, and 37 to the next meeting or August.

S. Hoffman: I second that.

H. Palacio: There were some that were already tabled.

B. Ellis: We will talk about that tomorrow as well

D. Burke: There are a few that are concurred in principal.

J. Lumpkin: Yes, and I would consider those to have been addressed if they were seen as particularly important.

D. Burke: The impact of cost savings if that can be added to the list, number 35.

S. Hoffman: I second that.

T. Inglesby: In favor?

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

T. Inglesby: Motion that the remaining recommendations that are concurred be approved. All in favor?

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

Vote on DEO Recommendations (#46-48) Tabled at April 22, 2011 Meeting

Thomas Inglesby, MD, Chair, OPHPR BSC

This portion has been tabled until tomorrow.

Report to BSC on External Peer Review of Career Epidemiology Field Officer Program (CEFO)

Herminia Palacio, MD, MPH, OPHPR BSC; Co-Chair, CEFO Review Workgroup
John R. Lumpkin, MD, MPH, OPHPR BSC; Co-Chair, CEFO Review Workgroup

The CEFO review workgroup members were:

- Herminia Palacio, MD, MPH (BSC member, Co-chair)
- David Gruber, MMAS
- Julia Gunn, RN, MPH
- John R. Lumpkin, MD, MPH (BSC member, Co-chair)
- Paul Halverson, DrPH, FACHE
- Jose Sanchez, MD, MPH

T. Inglesby: This is the first time this group has been presented to the BSC and so you are looking for approval to forward to the program am I correct?

Herminia Palacio: Correct. We had the pleasure of reviewing the CEFO program. Dr. Lumpkin and I co-chaired this group together.

The objectives were to:

Review Objective (1)

- Delineate the strengths, weaknesses and opportunities for improvement regarding:
  - The ability of the CEFO program field assignees to support, enhance, and augment PHEP epidemiologic capabilities of key partners, and specifically the emergency preparedness directors and epidemiologists in state and local health departments
- The CEFO Program headquarters role in sustaining a strong field assignment program, including:
  - Staffing and organization of the headquarters office
  - Scientific, technical, administrative, and supervisory/mentoring support of field staff
  - Program and policy development

Review Objectives (2)

- Evaluate the significance of the contributions made by CEFOs at their respective health departments

- Evaluate the funding model for the CEFO program, including assessment of who benefits from the current model (equity among PHEP grantees) as well as optimal and sustainable models for funding of headquarters staff

To describe the funding mechanism for this program, the CEFOs are funded through the direct assistance mechanism. The PHEP grantees (state, local and territories public health departments) can request an epidemiologist and funds from the PHEP are withheld for the salary and benefits of that epidemiologist. The CEFO is a federal employee.

Our workgroup members consisted of Dr. John Lumpkin and me serving as Co-chairs. Other members included Mr. David Gruber, Ms. Julia Gunn, Dr. Paul Halverson, and Dr. Jose Sanchez. Our review process timeline included a pre-meeting webinar on June 20, 2011 to orient workgroup members with background materials and specific review questions. The workgroup meeting was held on June 29 - July 1, 2011 where we heard findings from surveys of CEFOs and program stakeholders, listened to presentations from stakeholder and CEFO panels, which included state preparedness directors, state health officials and epidemiologists, local health officials, and CEFOs. As well, we were afforded the opportunity to ask questions of the different stakeholders. There was also a review of CEFO quarterly reports and publications. Post-meeting activities included:

- September 14, 2011, BSC meeting: deliberate on workgroup's findings and vote on final recommendations to OPHPR leadership.
- April 2012, BSC meeting: CEFO program provides formal response to recommendations.
- Annually: CEFO Program reports to BSC on implementation of recommendations until BSC votes all recommendations are adequately addressed

We brought our recommendations into a slate of general findings and then constructed findings specific to the objectives. We had two general findings.

General Findings (1)

- We found ample evidence to support the finding that CEFOs support, enhance and augment PHEP epidemiologic capabilities.
- However, the workgroup is concerned that the current funding strategy poses significant risk to the program's sustainability.

General Findings (2)

- Response to all-hazards events requires utilization of diverse skills and approaches:
    - Need to be applied in situations that are variable from jurisdiction to jurisdiction
    - Flexibility in meeting diverse needs of multiple jurisdictions is one of the strong points of the CEFO program
- High level of satisfaction among CEFO stakeholders and CEFOs themselves.
- CEFOs are impressive as to their qualifications, duties, and productivity.
- CEFO program adds significant value to the sponsoring jurisdictions.

In our remaining findings were:

- Lack of clarity as to the mission and vision and strategic direction of the program.
- Placement of CEFOs is dependent on the willingness of a jurisdiction to allocate PHEP funding
    - Unclear why some jurisdictions had multiple CEFOs and others had none, including those that expressed interest.

New York, as an example, had two CEFOs but some jurisdictions had none, and it was not completely clear as to why that could not be rectified in some way so that if a jurisdiction wanted a CEFO they could obtain one.

- Quantifiable measures of success were not presented.
- Changing needs in preparedness epidemiology, (e.g., informatics) at the same time resources are restricted or declining.
- Need for an overarching strategy for performance, including a gap analysis for jurisdictional needs.

In response to those findings, we suggested the following recommendations: the CEFO Program should develop a long-term strategic plan that should be informed by an initial gap analysis of jurisdictional needs for the services provided by CEFOs; and the CEFO Program should develop, implement and measure performance metrics, which provides empirical data that accurately reflects CEFO program successes/challenges and areas for improvement.

The next group of findings were:

- The CEFO program should be considered for expansion should funds become available in the future.
- Current funding strategy favors CEFO placements in state agencies (proportion in states outweighs tribal, territorial and local health departments).
- Concerned that the current funding strategy poses significant risk to its sustainability.

There was some geographical diversity, and it was unclear the way it was worded if locals and territories could request a CEFO. So there was discussion about changes in the way funding occurs or some better alignment.

We recommended that they explore alternative funding sources that preserve flexibility and simplicity of the program and preserve OPHPR's role as the program administrator:

- Allow jurisdictions to use multiple, non-PHEP CDC funding sources.
- Explore other internal funding sources by cross-leveraging resources at other CDC Centers, Institutes, and Offices (CIOs)
- Explore non-CDC external funding sources.
- Enable jurisdictions to use other resources under their control to fund the CEFO.
- Enable jurisdictions to share a CEFO.

All of these mechanisms were received by the workgroup with the caveat that leadership and oversight remain with OPHPR.

Another group of findings were composed around administration and management. Our findings were:

- Administrative supervisory management is strong.
- Enhancements could be made in two specific areas:
    - Scientific support
        - Need facilitated access to specific scientific technical support, such as informatics and statistics
    - Communication with jurisdictional supervisors
        - Need enhanced communication between the OPHPR supervisor and the field supervisors

We also encourage efforts identified by CEFO management to standardize quarterly reporting to enhance their ability to prepare statistical reports.

To those findings, the recommendation was that the CEFO program should clarify supervision and coordination of CEFO supervisor management by implementing the following:

- Ensuring improved coordination between CDC and field supervisors.
- Exploring the feasibility of providing greater access to and use of scientific support and consultation as a core headquarters management capability.
- Adopting a pro-active (lean forward) approach to linking CEFOs with key operational resources across CDC CIOs, such as informatics, statistics, GIS.

We also had findings regarding the CEFOs themselves.

- The workgroup was impressed with the high quality of the CEFOs.
- The two-year initial field placement followed by optional annual renewal created significant anxiety and insecurity.
- Anecdotal evidence indicated that this reduced the potential pool of high quality CEFOs.
- Some CEFOs also stated concern about the perceived lack of value that CDC places on CEFO field work assignment and subsequent implications for career advancement.

Our recommendation was that the CEFO program strategy and policy should ensure greater assurance to CEFOs of continued employment and opportunities for advancement within the context of available funding levels.

There were a few other findings and recommendations.

Findings:

- Within the scope of the PHEP Cooperative Agreement guidance, field placements were diverse in their requirements for skill sets and scope of responsibility.
- Further, the tasks of field epidemiology are expanding due to advancements in information technology and the demands of all-hazards response.

Recommendation:

- The CEFO program should ensure CEFOs have a defined set of core competencies through:
    - Defining the basic set of core competencies.
    - Ensuring this includes cross-cutting competencies such as leadership, policy analysis, development, and informatics.
    - Ensuring cross-discipline competencies, including environmental and chronic disease epidemiology, are addressed.
    - Ensuring continuous professional development throughout the CEFO tenure.

Findings:

- Stakeholders emphasized the unique value of the CEFOs' ability to facilitate linking state/local/tribal/territorial jurisdictions to additional Federal resources and expertise.
- Stakeholders and CEFOs noted the importance of providing CDC with real-time field information and perspectives ("boots on the ground").

Recommendation:

- CDC leadership should reinforce and expand the role of the CEFO as a facilitator of bi-directional communication and coordination between CDC and assignee jurisdictions.

Findings:

- Stakeholders and CEFOs reported on CEFO enhancements in epidemiology systems, training, drills, exercises, etc.
- Work products, enhancements to system operations, and other innovations developed by CEFOs are of value to the entire public health preparedness field.

Recommendation:

- CEFO program should ensure widespread dissemination of CEFO products.

Discussion and Recommendations

Thomas Inglesby, MD, Chair, OPHPR BSC

S. Hoffman: One question is did you get some feedback from the program? Some recommendations are vague and some will require funding, so I want some sense about what they feel about it and whether they are realistic and doable.

J. Horan: I am very glad funding has come up like this from an external review. I do not know exactly what we are going to do about that. Our stakeholders are very interested in keeping their CEFO and we are looking at how to sustain that program.

B. Ellis: We looked at the recommendations and the one recommendation that gave me some concern was revised with language that added "within the context of available funding." We are looking at the suggestion of multiple funding streams.

D. Arnold: I am very interested in this program and there is potential crossover with other federal agencies. There is also the Health Information Exchange and one of the things we pushed for is public health emphasis. CEFOs would fit well within that. They are looking for SMEs to help them look at things from this perspective.

T. Inglesby: Do you all have a separate budget other than what comes in from PHEP?

J. Horan: My staff and I are funded through headquarters. All officers are funded under the PHEP.

T. Inglesby: And how much do you all get for this program?

J. Horan: I do not have that dollar figure.

V. Kokor: It is about $922,000.

T. Inglesby: How are CEFO's hired and what is their background?

J. Horan: If a state requests a CEFO, we post it on USAJobs. We also have internal transfer as another mechanism. Their level of experience also varies.

J. Lumpkin: There is a ceiling.

J. Horan: They are all ceiling exempt FTEs.

D. Sosin: The ceiling is not currently a resource constraint. So at the moment it is not an issue but because the funding stream is separate there is question on how

much a program can commit. There was a recognition, about 25 years ago, regarding getting field staff out like we did for communicable disease and we have leveraged various pots of money over the last 15 years that have evolved from epidemiologic capacity to preparedness and how epidemiologic capacity can help to better preparedness. Tommy Thompson said that all states should have a CEFO to assist with preparedness. The challenge can be what is the appropriate scope and how do you justify some activities compared to other demands on preparedness.

J. Lumpkin: One of the great things about this program is it is free head count for CDC and the state, so this fills some of those voids.

T. Inglesby: Have there been more requests than you can fill?

J. Horan: It waxes and wanes.

T. Inglesby: What is the advantage of using a CEFO?

J. Horan: One factor can be the quality of the person is viewed as extremely high. When we have had EIS field assignees that have done well in their position, they want to continue that person in that position and this often is an easier way for states to get these people.

H. Palacio: And CDC can pay that higher salary for that level of expertise that states often cannot afford.

D. Burke: Who do they work for or where is their loyalty?

D. Sosin: Their role is to support the needs of the state and their employment is through CDC.

J. Lumpkin: And their roles change. They can at some point become supervisors in the state.

T. Inglesby: So you said some CEFOs felt a lack of support.

H. Palacio: There was a concern, and it is an undercurrent of anxiety, not necessarily lack of support. They were far away and felt sort of the out of sight out of mind. They wanted to make sure they were on the radar screen when opportunities come about.

D. Sosin: And this is an inherent thing with field officers having been one myself.

H. Palacio: And it came through enough that we felt we needed to address it.

T. Inglesby: What form or reassurance would they have?

J. Lumpkin: Dissemination of their work products was one way to give them credit and assure them that their work is valued.

T. Inglesby: What happens after the 2 years?

J. Horan: The funding agency can decide if they want to renew for another year. At the end of the two years many of them decide to do this again and again.

T. Inglesby: If they are not picked up?

J. Horan: They can go to another area that has funding.

D. Sosin: There is a process where new officers are on a probationary period, but we still have to find them another job if for some reason something does not work out. When the direct assistant dries up, we have to find them another position.

J. Lumpkin: And that relates to our flexibility of funding recommendation and having a recommendation to keep them.

S. Phillip: The EIS officer program is pretty well known. But CEFOs are not well known so there needs to be more marketing of that program so people know it is a good product.

E. Vaughan: Someone mentioned there were 31 CEFOs in 25 states and I am thinking about the challenge in evaluating the success of the program because of the small sample size. Maybe there could be some language about looking for innovative ways of evaluating the success of this program in consideration of their small sample size. I am just concerned that it may be unfair to do the same evaluation approach that we use for other programs. Also, the standardized quarterly reporting, recommendation 2, causes problems. So we need innovative ways to identify gaps and then how this program fills those gaps can be used to argue for clarifying their importance.

H. Palacio: They realized they had an issue with them and they were trying to fix. We started to address that and backed our way out of that.

D. Sosin: We could come up with measures but it may have limited value, and if so, then we may need to concentrate our efforts on something else.

J. Lumpkin: It could be a story bank for those who have more interest in that.

H. Palacio: And it provides an amplifier.

E. Vaughan: And that is why I asked if quantitative metrics could do that and show the impact of the program. That is where a large impact could be missed.

T. Inglesby: So would a shorter version of this be better?

J. Lumpkin: I would say we need to look at both. If you are talking to a funder in CDC, they want both.

H. Palacio: We did receive quite a number of surveys in our background material and there was tremendous variability in the not applicable category. CEFOs may report to an all-hazards preparedness person or a non all-hazards preparedness person. If they were reporting to the preparedness person, then you would get feedback on the preparedness standpoint, but if that was not something their direct report was working on, then it would be a not applicable. But it was not clear that the universe of activities was well defined.

J. Muckstadt: Was there any consistency depending on the type of location?

J. Horan: What they work on is building capacity, developing and enhancing collaborations and partnerships, provide training and communications, and some developing understanding or technical aspects. Some may be working on one or all of those. And that may be location specific.

J. Muckstadt: So how do you measure that? Any one person may be more productive than another.

J. Horan: I like John Lumpkin's view that we may need to use a story bank.

E. Vaughan: And it may be useful to tie it into the capabilities of this office. It gives more weight to the activities where this individual has made it possible to reach hard to reach populations, for example. So if a person is doing activities that relate to that high priority, that should have a lot of weight and statistically it may not show up. So it may need to be a multi-method approach to show that.

D. Sosin: Historically the way we show that is in our grant guidance. I think what the workgroup laid out with competencies being a menu is a more effective way to address this.

D. Burke: If we took care of Recommendation 1, would it not take care of 2? I still do not know how important these people are in the locale. I do not have that baseline. I would like to see that information as to how this is presented and are they indeed plugging gaps in for folks who do not have preparedness staff.

B. Ellis: In territories we could be looking at a huge amount of the PHEP being used to sustain a CEFO. So that is why multiple sources of funding would help.

D. Sosin: And that is why it would be helpful to have your input on that strategy. Another recommendation was the two-way communication. Having CEFOs in New York City were extremely valuable during the Hurricane Irene response and being able to share their information with neighboring states was very helpful.

S. Hoffman: And there were some suggestions for revisions, so we need to wordsmith those.

T. Inglesby: So John, you want to do that now?

J. Lumpkin: Revision to Recommendation 2, the CEFO program should measure its performance by: A) implementing and measuring performance metrics that would enable CDC officials to be able to provide empirical data that accurately reflects program successes and challenges and areas for improvement, and B) using other innovative approaches.

Revision to Recommendation 9, CDC and the CEFO program should enhance the visibility of the program by promoting the products of the CEFO's work, such as publishing an annual report demonstrating the success of the program.

S. Hoffman: Are there other suggestions we can give them about how to do this?

D. Burke: The name CEFO does not really have a name value and does not really say what they are doing. Change it to something that does have value like preparedness counseling or counselor or consultant, something that is more descriptive of why they are there.

S. Phillip: And you do not want to be seen as a CDC placement service.

T. Inglesby: So add to visibility and brand.

S. Phillip: I agree.

Vote on Recommendations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: So we need to move on to voting.

H. Palacio: I move that the recommendations including the amendments be forwarded to be approved by the full BSC with the revisions for 2 and 9 added to that.

J. Lumpkin: I second it.

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

Public Comment Period (Day 1)

T. Inglesby: Now we are to get comments from the public.

[No comments from the public.]

J. Muckstadt: Tomorrow we are going to look at the review that I prepared, so I am giving you a homework assignment. Look at Section 6 of your report and you will see my report. I suggest you look at pages 9 through 14. I will go through very quickly what the recommendations and challenges are. Please note that there was no data for us to work with. Then I will move on to the science that is associated with addressing the questions and illustrate how that science was employed here. I will give some background on science logistics to help you as well and things going on in CDC related to the issues being raised. If you do that, we can move rather quickly tomorrow.

T. Inglesby: The second assignment is to answer the three questions that Dr. Khan has posed to us. And the third assignment is the DSAT review report - we will hear program responses from that review tomorrow. Meeting adjourned.

Adjourn (Day 1)

Thursday, September 15

Welcome – Meeting Convenes for Day 2

Thomas Inglesby, MD, Chair, OPHPR BSC

Roll call was taken by Dr. Ellis to ensure quorum and quorum was met.

Vote on DEO Recommendations (#46-48) Tabled at April 22, 2011 Meeting

Thomas Inglesby, MD, Chair, OPHPR BSC

L. Rowitz: We looked over Recommendations 46-48, and we decided that those are repetitious and are covered in recommendations that were already provided. We have decided to not move forward on those. They are regarding strategic plans and they have already done that for the DEO and the Office, so there is no need to move those forward.

S. Hoffman: And board needs to vote on that.

T. Inglesby: If there are no other comments or questions.

L. Rowitz: I recommend that we drop those recommendations

S. Hoffman: Second.

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

BSC Peer Review Topics for FY2012 / Calendar of BSC Meetings

Barbara Ellis, PhD, Associate Director for Science, OPHPR

T. Inglesby: The next subject is to determine our next meeting. This meeting's topics will be in regards to the workgroup who reviewed the PERRC Program.

They will present their recommendations for our consideration. It is also an opportunity for us as a group to understand the informational elements of OPHPR. Lastly, probably between now and January, OPHPR would like to initiate a new external program review. They would like to hear from us regarding any ideas we may have of what that review topic should be.

The next in-person meeting is scheduled for April. In the past, one of our challenges has been availability. We are being asked to be flexible for the April meeting and also for the November meeting. The agenda is completely blank. The PERRC review will have already been examined with maybe some things carried forward, and very little else to look at. So we can look at advising on issues that are important to the Board. What we want to do is hear from Dan on issues that are on OPHPR's agenda and then hear from members.

Another way of us working with OPHPR is for us to get informational briefings with questions for us to react to at the end of the briefing. If there are things we want to understand better, we should put those on the table and obtain informational briefings on those to talk about at the next meeting or at least through a conference call.

D. Sosin: We will continue to do reviews as required. During the day today we need to line up those briefing and discussion topics where we can have input and advice and gain deeper understanding to those topics that you would like more information on. Reviews are challenging because they require significant planning. We currently have nothing cued up for general topics. There was discuss of the need for additional information on measures and indices, ideas on how to do a better job of measuring our capabilities and performance, better understanding of where is the science, and who should we be calling on to gain better understanding. We were also talking about our after-action processes with the DEO and ways that we get data and evaluations there. What we want to do in the session this morning is brainstorm on issues that you think we should work on.

T. Inglesby: Any thoughts?

H. Palacio: I applaud the interest in having an additional review, but bringing up another review so quickly might actually detract from your efforts. You may need to focus on implementing those changes already suggested.

D. Sosin: I appreciate your consideration of our workload and the fiscal implications they incur. Before we convene a panel, it is usually a 4 to 6 week timeframe of preplanning. We are looking at a review of late spring or summer, so we need to get those ideas on the table to do that preplanning.

B. Ellis: Yes, like in the CEFO, it takes about 9 months just to plan ahead so getting those ideas in advance would be helpful.

D. Burke: The reviews were regarding your organization. So do we want to stay in the organization framework? Is that easier to frame?

D. Sosin: The charter says that you can look across centers and doing that can cause some complexity because we are not necessarily experts on other centers. Therefore, we may not be able to answer all of your questions. But for future meetings, we can make those folks available and do meetings together to address those questions.

T. Inglesby: We talked about looking at the laboratory science and heard that a lot of that work is not going on in OPHPR but might be funded by OPHPR. We could probably set up a full review of that portfolio even though it is being executed by another Center.

D. Sosin: Yes, we can do that.

D. Burke: What are the other boards in CDC? If we are going to start to look across CDC, we need to look at that so that we can structure our thoughts.

D. Sosin: We are a coordinating office, and there are many offices that come together to do preparedness. What we do is very crosscutting. The mechanics of that can get in the way, but we will figure that out as we go.

T. Inglesby: Can we get the names of those boards and the reviews of those boards? We can see what they said and did.

D. Sosin: Sure.

M. Gilchrist: In the Laboratory Health Group, there is not a big radiological element. It is a complex interface with many parts of CDC, and it would be good to do it on this board rather than one of the others.

T. Inglesby: Why is that?

M. Gilchrist: Because those offices would focus on their particular issues whereas this group is more likely to take a look at the overall picture. Right now it is a quiet laboratory response environment, but when activated, it is a different story in LRN.

D. Sosin: The LRN biological side did conduct a peer review of their strategy and direction. There were a lot of questions that remained after that review. You have to decide if you are going to focus on the system or the science and that can be a challenge. So an inter-board or multi-center view is possible.

L. Rowitz: I have a wish list. I think we should have a discussion on the PAPHA legislation and where it is going and any other policy issues. Nicky would be a good person to have here for that discussion. Second on my wish list is to look at the preparedness research agenda without the PERRCs, what direction we need to take, how to form partnerships, and how to work together jointly rather than having the research at an individual institution. We may be able to leverage money better if we have two or three agencies working together.

D. Sosin: Is that an extramural activity?

L. Rowitz: Yes. We should also have a discussion with HRSA to look at the training centers if the PERLC go away. That can be an interesting relationship with two governmental agencies working together, and it can be a complicated. We also need to have a discussion with Dr. Frieden on where he sees preparedness going in the future.

T. Inglesby: I would like to add the preparedness index discussion. It would be great to get a briefing to see where it is headed. A briefing on the budget would be good as well. We had a high-level view yesterday, but I would like to know the purposes of the programs and not just how much you spent. It would be nice to know, for example, how much you spent on laboratories. It will allow us to ask better questions and to become wiser.

H. Palacio: There is a lot of effort on countermeasures, and there is a lot of surveillance activity. Some of the science behind that needs to be looked at as well.

T. Inglesby: It would be nice to get a good briefing on that. There was a big review on that recently. So we should figure out what questions we have and get answers to that.

D. Sosin: This is an area where our center plays more of a consumer role. We are looking for direction on how to leverage in that area and be able to put issues on the table.

S. Phillip: We have done a lot of looking in, but I guess looking out are there topics or areas that external board members can help with? What are external challenges that the Center is having that we as a board can make recommendations to you and help you with those frustrations? So think about external things that we can advise and give leverage to.

D. Sosin: Thanks Sally for that. So we need to look at a briefing on review and division topics. We want this to be like a family structure to look at challenges and get your honest feedback.

E. Vaughan: This is a content topic about organizational issues. There are some new models of preparedness and what it means to be a resilient society. These new models are being incorporated into policy regarding resilience, and the models have a lot of implications. They are more decentralized. They require more involvement of private-public sector relationships to increase that resilience and looks at how communities and others can be involved in preparedness. So we can bring some of these new dynamic models to keep this office fresh and that is useful for funding, figuring out what is viable, what are challenges, and new ways to think about how we look at preparedness. I am seeing it applied in policy and in funding.

T. Inglesby: Would that be something we would talk about Dan?

D. Sosin: Yes, and you as members of the board have expertise and knowledge that we do not know about. Some of these briefs can be done by you on those

types of things. They can lead to the opportunity for discussion or follow-up and uncover new things to be integrated that may be useful to us.

T. Inglesby: Yes, and we could work those into the agenda for a concise briefing.

D. Burke: We could have a briefing around an event and how well we did in responding in the DEO. I would like to see what has been done. For the H1N1 pandemic was there an internal critique of what happened?

P. Navin: Yes, there was. We can contact the program that was the lead for that response and see if the report has been cleared, and if so, provide it to you.

D. Sosin: There are documents produced on that. But what we share with you has to be able to be shared with the public. We have to make sure there is no sensitive information.

D. Burke: So much of what you have to worry about has a security dimension to it, and so if we do not review that, who does? I am perfectly happy if someone else is doing that, but if not, then that is a concern.

T. Inglesby: If there is something we want to review, we should ask to review it and do it through a closed session if needed.

D. Sosin: We will figure out how to retain material that should not be shared more broadly. We do not want to take things off the table but will structure it in a way that it protects the sensitivity.

P. Quinlisk: Is there a place for looking at the new uses of technology and opportunities and how they are being used in an emergency situation? I do not know if there is someone who is looking at that in a systematic approach.

T. Inglesby: Do you think those are happening way out in the field versus at CDC?

P. Quinlisk: I think the states are behind.

T. Inglesby: So is the state advising CDC or vice versa?

P. Quinlisk: I do not think it is telling but more sharing what is new out there. We need a more systematic approach for looking at that and things that are being done with electronic medical records and not necessarily for emergency preparedness but how we can use those to make sure our response is all that it can be.

D. Sosin: We can look at how OPHPR does a better job of tech watches. We are probably more reactive than proactive. We can look at the processes that are used.

S. Hoffman: In response to Patty's comment, I have written a lot on electronic health records, and I co-authored with my husband, who is a computer science expert and advises on the technology. We can talk about liabilities,

vulnerabilities, risks, etc. Also we have not focused on legal and ethical issues, which is my area of expertise. I am willing to be helpful in those areas as well, and I do not want those to get lost among other topics.

D. Arnold: I am on the HIE Board for Illinois. With grants tracking, we are doing continuous auditing and are hoping to put in some metrics. Preparedness is a good place to do this. We are looking at time scales or measuring population bases to look at outcomes. We could produce a guidance for HIE. We do not have the same clearance process in many of these regional centers. If the CDC gave some guidance it would be a great step forward.

T. Inglesby: Those are great suggestions. Now we will turn it over to Jack.

Report to BSC on External Peer Review of Division of Strategic National Stockpile (DSNS)

Jack Muckstadt, PhD, OPHPR BSC; Co-Chair, DSNS Panel

The DSNS review workgroup members were:

- Dr. Jack Muckstadt (BSC member, Chair)
- Dr. Margaret Brandeau
- Dr. Aruna Apte
- Ms. Patricia Kelly
- Mr. Steve Miers
- Mr. Kenneth Sturrock

I hope you all did your homework last night. Many things have changed, and I suspect that Greg Burel and Sue Gorman will comment on those. We will also talk about the science of response logistics. The word “model” has come up several times in our discussion; model means a lot of different things for different people. A couple of years ago I gave a talk at Cornell and I was explaining what we are doing in preparedness. A gentleman said “I listened to your conversation, and I am not sure I understand what you mean by model. The model I understand is Marilyn Monroe, so we need to make sure the way we use the word model is clear.”

This review focused on the comparison of the current SNS “hub and spoke” model for inventory storage and delivery versus the forward deployment and maintenance of assets under federal control, in the context of a Cities Readiness Initiative (CRI) inhalation anthrax-related event. For the purposes of this review, the scope focused on an inhalation anthrax scenario that would require prophylaxis of the potentially exposed populations within 48 hours.

We had four questions that came up through that review.

1. Assuming a community can begin forwarding materiel to their Points of Dispensing (PODs) at hour 12 after making a request, is the current hub-and-spoke model adequate for responding to a CRI event?
2. If the community can begin using materiel at 3, 6, or 9 hours after making a request, taking into account the 72 CRI cities and their populations, along with the requirement of having to respond to simultaneous events in three cities, how much materiel should be forward deployed and in what locations in order to support this type of programmatic change, if it were deemed beneficial?

3. What are the pros and cons associated with the procurement of additional inventory, storage locations, and manpower that would be needed to manage the storage locations, perform annual inventories, and provide security; and the potential need for movement of materiel from multiple locations to one location where it would be needed?
4. Would there be other more efficient alternatives to the hub and spoke model in a CRI event?

What you will see is that there are some common threads in all of them, particularly the second point. It is important to think about when looking at model, how much material will have to be put in place to make one of these systems functional. That requires a lot of information to review to find that answer.

Our workgroup consisted of me as the Chair, Dr. Margaret Brandeau, Dr. Aruna Apte, Ms. Patricia Kelly, Mr. Steve Miers, and Mr. Kenneth Sturrock. Some members had experience at executing programs at the local levels and others with working in academics. I have a lot of experience in working with companies, and as a consequence I look at ways you can think about these problems.

We had pre-meeting webinars on April 17, 2009 and July 17, 2009. Our workgroup meeting was held on July 28-30, 2009. That meeting afforded the opportunity to review extensive background materials from DSNS; hear presentations from DSNS staff on state preparedness efforts, modeling studies, simulations for exercising response capabilities; listen to input from state and local SNS coordinator presentations; and participate in question and answer sessions. Today of course is our post-meeting where the BSC deliberates on the workgroup's findings and votes on final recommendations to OPHPR leadership. We were assisted by Sue Gorman through this and Greg Burel intermittently. We appreciate their help.

We were not able to adequately address the questions because we do not have the data. Data comes in obvious forms. There is data on cost and there is also data you want for adequate logistic issues. Some information is not released, and so it is a little difficult to make some recommendations.

T. Inglesby: Was the data not there or just not released?

Both. Specific data needed to answer the questions did not exist or had not been provided to OPHPR in a usable form at the time of the review. The panelists unanimously agreed that DSNS must aggressively grow its modeling, simulation, and data collection efforts.

Our recommendation to those findings was to expand and further develop models that can evaluate the logistical consequences, health benefits, and costs of alternative supply chain configurations. DSNS has made impressive progress in their modeling efforts and the use of such modeling efforts to support informed decision making, from the design of Points of Dispensing Stations (PODS) to the detailed evaluation of nationwide SNS deployment. We recommend that these efforts be broadened to include the evaluation of additional logistical consequences, health benefits, and costs of alternative supply chain configurations. Specifically, we recommend that DSNS:

- Create models that are simple, focused and inexpensive, while still oriented toward the operations of the entire response supply chain.
- Use such models to improve the design and operation of the response supply chain. Develop more advanced simulation and analytic models to assist in the creation and evaluation of components of and the entire response supply chain.

- Apply portions of their existing detailed simulation models for training and simulation.
- Create cost-based models to evaluate consequences of alternative supply chain configurations.

DSNS has built some models and it is expensive to model an exercise but it lets you comprehend the consequence of policy. We did some mathematically-based models as well as some cost-based models. The models must be designed so that they can be used effectively. You want to look at cost and effectiveness.

Whatever plans you put forth will not play out exactly as you anticipated. A scenario is an identification of what might happen during an event. The command and control system that you are going to have in place will define your scenario. In planning, you create various scenarios, choose a strategy, and predict what would happen in those scenarios. You can tradeoff risks versus cost and figure out what the consequences are going to be.

In the case of the flu, you have to have some situational awareness but also a prediction of what you think will happen and then a plan of how to allocate materials. There are lots of open questions that need to be undertaken to get a grasp on the logistics of this. Receiving material, documenting that you have got it, pulling it out, documenting when it was pulled, etc. -- you must do those and do those in a repeatable manner. You must also think about policy. The commercial world does this well. If you are going to think about how you are going to operate that adds in another level of complexity.

Our group designed some models of how you could do this. The cost-based model is called RESCO. Another model is called ESCOE. You have a set of steps to evaluate a scenario. You first construct a network that tells where the locations are and what are the capabilities. Second, how long will it take to move materiel? What inventory is required? What are your capabilities? Then you look at PODS and run an experiment. The experiment is a problematic world view that lets you see what the consequences of your design are. You run the program and you get an output. You create a modeling environment based on some scenario, and this will let you determine how many people you are able to service. You want to have a range of potential risks and consequences.

ESCOE was developed by a couple of graduate students at Cornell, and you did not need a computer science degree to do this. These students got an award for their work. Our recommendations are not actionable items but one suggestion we have is to have graduate students work with you at CDC, and you can use their knowledge to complement the skills you all already have. I have worked with Georgia Tech on logistics, but there are other schools that also do this well. Each has their own viewpoints, so you may want to broaden your scope of universities you work with.

The remaining recommendations we suggested were:

- Collect the data needed to support model-based decision making.
- Use the models to answer the questions in the scope of review.
- Expand the use of continuous improvement techniques in all aspects of DSNS response.

We also asked that the Program give strong consideration to some other sections.

- Strong Consideration (1) - Continue to focus on the ‘last mile’ of the response system.
    - This involves enhancement of dispensing capacity, including the use of models to help evaluate consequences of design, and develop realistic modes of

dispensing (for example, to understand when and how various components of dispensing can become operational in an emergency).

- Strong Consideration (2) - Identify and eliminate barriers to efficient medication distribution and dispensing.
    - For example, DSNS may wish to have legal counsel revisit the interpretation of the Public Readiness and Emergency Preparedness (PREP) Act liability coverage in order to find a better solution for legal use of SNS countermeasures in existing packaging (rather than the current system involving Emergency Use Authorization).
- Strong Consideration (3) - Consider cost and resource consequences of alternative supply chain configurations and inventory management procedures (warehouses, material, locations, response times) to DSNS overall.
    - DSNS funds are limited and decisions about investments and the response supply chain must be evaluated in the context of the overall DSNS budget.
- Strong Consideration (4) - Partner with universities to enhance simulation and analytic modeling capabilities.
    - The DSNS should consider working more closely with faculty and students from several universities to augment and enhance its modeling capabilities. Student interns would be an excellent and cost effective source of assistance.

Comments from Greg Burel, Director, Division of Strategic National Stockpile

There have been some updates since this review. We have pondered about if we even asked the questions the right way. We have a very robust suite of models that we offer to our state and local partners so that they can work with us. We are continuing to provide states with access to models that they would not be able to afford. Georgia Tech offers them access to models with PODS. We also offer models on transportation to anticipate accidents or routing. We look at a number of modalities for dispensing. We also concentrate on the analytical branch. They inform the budget formulation decisions with models that will help us reformulate our processes.

We are continuing to collect more data from states and locals to help drive our decisions. This ensures that we are matched in our distribution to those modalities. We look at timelines to see if we can hit that modality in that timeline, and we have come up with some pretty good solutions that will allow us to move prophylaxis materials within 6 hours of a decision. That requires some pretty good investments on our part. We are working on a project plan now to do this with the states to help them come up with a plan as well.

We also found through backwards modeling that we can complete distribution by hour 4 to 5 rather than hour 13, so we are beating the timeframes we have advertised to those district. We need to go back and reconfigure and match those again up to the states. And we are going to continue revising on this route.

Discussion and Recommendations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: Any other questions?

G. Burel: When we did our distribution campaign in H1N1. We dispersed about a fourth of the antiviral stock, and we learned a lot of things. Our distribution capabilities are robust and can meet timeframes. In some cases we were faster. This was the first massive distribution of any stockpile, and it went well. Now for other areas, we have been planning for pandemic flu. We have matched states to our capabilities and we feel very confident about our progress.

T. Inglesby: Were you involved in McKesson's distribution of vaccine?

G. Burel: No.

T. Inglesby: Will they be used the same way for vaccine?

G. Burel: I cannot speak to that. Our plans have never called for reaching those partners. We made good connections to the supply chain sector so we can understand real time information. We used that information to see how it will relate to our supply chain. If our supplier could not act as quickly, we could go another route.

S. Hoffman: I remember from prior presentation the discussion of replacing the stockpile because of expiration dates. With funding cuts and so on, what is the situation with that?

G. Burel: We continue to look at expiratory products. We are beginning to understand what that does in terms of cost and whether that is helpful in some situations or not. We are trying to figure that into the budget, but we can replace expiring drugs that need to be replaced over the next several years. We look at reverse distribution models where these products can be used in a different way when expired. We are doing a lot of work there. We examined shelf life extension as well, and the DoD entered into this arena with the FDA. DoD makes a lot of sense on this. They used to buy large supply-houses of drugs but they have gone to just in time levels. They have full expectation that they will use what they are sitting on, but we hope we do not have to use what we are sitting on. The way it works is we pull samples by lot numbers and we send it to the FDA to determine efficacy, and they give us an extended date. We take that product to an FDA relabeler and after relabeling it is put back into stock. This is a cumbersome process, so we have to consider is there a time factor we cannot tolerate related to that or a cost.

J. Lumpkin: I am curious as to whether other alternatives have been explored. In Illinois, we were able to make an arrangement with a wholesaler to keep an active stockpile so when a hospital had an order, that order was taken from our stockpile and then we replenished our supply.

G. Burel: When we look at bringing in new products, we look at vendor-managed arrangements as you are describing. For some of the materials we hold such a large volume, vendors would not be willing to do those kinds of arrangements because it is more product than they actually sell. We have asked what percentage could you store and rotate for us and how much would repackaging be.

T. Inglesby: Do you want the board to continue to vote?

J. Muckstadt: I do not think there is a need to. I think they are moving forward on this. I would encourage them to build their modeling in the way we prescribe but I think they are moving in that direction.

S. Hoffman: So we can take a vote on that.

D. Arnold: This was a very good presentation. You talked about the real time corrective steps. Another important idea is the data captured in the real time sense and tracking the evolution of a response. In NIMS the respondent is looked at as equipment. You also have the ability to do an overview to examine what the regional differences are in one city versus another and what is causing these things to be different to give plans for consideration and alternative views.

J. Muckstadt: What you described are scenarios and the whole point of planning is to look at scenarios that might arise. We thought through two scenarios. If I were a terrorist with anthrax I would think about the day after Thanksgiving in New York City. It is a very busy day and lots of people have come to the city just to do their shopping. You may think about how you would dispense something in this situation. Another scenario is the day of a major football game. What if something was released in the middle of the field? In both of these situations the people exposed are not going to be in that area subsequent to exposure. So we have to think further than just dispersing to that area but have strategies that will reach much further.

T. Inglesby: Is that part of OPHPR's vision?

D. Burke: I want to know who looked at that and I see that as part of our mission in preparedness and I have not heard that. There is a bigger picture that needs to be considered. I do not know if there was an overall review. It may have been internally but has an external review been done in response to the panic?

G. Burel: The last mile is largely a matter of aligning plans to state plans and policy of who should get the materiel. In terms of internal reviews, there are very comprehensive reviews internally. Externally there are reviews going on with ASTHO and NACCHO.

T. Inglesby: Maybe we can get a brief on those internal and external reviews at our next session.

D. Sosin: The reviews have been about lessons learned and observations that led to different planning directions and ordinances ongoing. We can arrange for a briefing. We can go over those reports and distill for you information regarding the flu response, for example. It identified challenges and we are looking at creative ways to improve those challenge identified before the next event happens.

G. Burel: We are cognitive that our response to that sort of a natural pandemic event is very different from an immediate response to a CRI event. But we can use lessons learned for a CRI event.

M. Butel: What is the oversight and process to review the consistency and comprehensiveness of tools applied?

G. Burel: The SNS does a formalized evidence-based review of state plans for prophylaxis. It is the only review that I am aware of in the federal preparedness arena that a score is assigned that is evidence based. Can it continue to improve? Yes. What we are trying to figure out is how to go from storing in planning to make a predictive score of that plan.

J. Muckstadt: That is not easy to do. Three quarters of what was sent out was lost.

G. Burel: I do not know if that is accurate. We do not know what patient it was handed to, but we have a good account of what we sent out.

D. Arnold: We have a good tracking mechanism for that. It was applied in the state for countermeasures to make sure we had good clinical checks. We used iPads to collect data and that gives you real time information so you can match the predictive value with what is really happen. We are trying to find links.

K. Smith: It is the rare instance where the state is involved in the direct provision to a human being. So to get to the last mile you have to get down to the local level. We learned that as soon as you deliver directly to the private sector you lose a lot of opportunity. We have difficulty getting information from those physicians, and that is an added level of complexity that needs to be taken into account.

J. Muckstadt: Vaccines are a little different than distribution of pan flu countermeasures.

K. Smith: That is where the policy piece is so critical. It is hard for physicians to do that and to understand the need.

A. Khan: Greg, can you talk about the things you are doing with cost cutting?

G. Burel: We are analyzing what the real utility of pushback is and where do they need to live. We would likely look at eliminating standalone pushback sites.

That will save several million dollars a year. There are a lot of studies to see if we can get more out of what we have, and we are looking forward to seeing results of that.

T. Inglesby: What is the date on getting those results?

D. Sosin: About 18 months to see the first arm of results. So a good year and a half before we have an initial sense.

G. Burel: We also have investments in federal medical stations. We have found some innovative ways to approach the thing we do. We have engaged with the General Services Administration (GSA), and we are looking at packaging ideas that will save us space.

T. Inglesby: It would be great to get a presentation or a briefing on that topic.

G. Burel: I would be happy to do that. We have a lot of great people at SNS who think about these things and figure out ways to control our costs.

Vote on Recommendations

Thomas Inglesby, MD, Chair, OPHPR BSC

J. Muckstadt: I move that the recommendations be tabled.

S. Hoffman: That means it comes back. So you want it not to come back?

M. Butel: What about the recommendations that came out of that? Where will that be placed?

B. Ellis: Now that the board has deliberated on this, it is public record. You would not be hearing back on it.

D. Burke: We heard that there was nothing to draw a conclusion on, so I do not know if it is the right response for the committee to say that this has been addressed. I do not want to say the topic has been addressed and that we will not revisit it because the recommendations of this group have been satisfactorily addressed.

S. Hoffman: That is not what we are saying. If we vote to approve the report they are bound by it and they have to continue to report. We have said that Greg has to come back and give us more information. We do not want these to be binding on that program.

B. Ellis: It is not that the Board is not accepting the report, but in terms of the recommendation, Jack feels that many of these recommendations are being worked on by the Program.

J. Muckstadt: Yes, to do this analysis, they are going to have to collect data. We have to assure they are doing that, and they will report back on those data later.

E. MacKenzie: Well would that not be the recommendation then? I am uneasy about dismissing the report.

J. Lumpkin: Why do we not first accept the report and add a motion that we believe further follow-up on the recommendations is needed for the future?

S. Hoffman: But is that procedurally appropriate? Before we vote on that I would want to make sure it is procedurally appropriate.

B. Ellis: It is. The recommendations are not consensus required. You can change them.

D. Burke: So we accept the report but then what is the expectation for them to come back to us with additional information?

D. Sosin: If you want to continue to see us address these issues and report back as to how we are doing, we can give data as necessary.

D. Burke: Now I am comfortable.

S. Hoffman: So report on all the recommendations.

T. Inglesby: Yes, it is only four.

D. Burke: I think it is a reasonable request.

G. Burel: I can do that.

D. Sosin: We discussed where we are now, but it is not clear from the recommendation that this is ongoing. You can suggest how that will be presented. Is it annually, we give you updates? Do you want to know what is happening so far and what are new activities at each report out?

T. Inglesby: A new motion would be we approve the report and recommendations and hope for an update on some future appropriate date.

D. Burke: I would like to see more on that last mile and what we know and do not know about that.

D. Sosin: I think we got a briefing topic with some of that about use of models.

J. Muckstadt: The comment they put in the report was outside the realm of what we asked for.

D. Sosin: We need to address that as a separate issue.

D. Burke: I want to know what happened in the last mile.

T. Inglesby: So we can do that in addition to the report. Greg can you respond to that and give us an update?

G. Burel: Yes.

J. Lumpkin: I am in favor of the direction we are going. We have to remember that we may need to go back and figure out who got what if there is a recall. There needs to be a conversation on ethical issues in dealing with this and do you spend more time on documenting or getting it delivered. That may be a valid conversation either in this report or a separate item.

T. Inglesby: What is the motion?

D. Burke: I agree we accept report and recommendation.

M. Butel: Second

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

"Ask-the-Board" Session

RADM Ali S. Khan, MD, MPH, Director, OPHPR

Given the time limitations, we ask that each Board Member, Ex Officio, and liaison representative consider a single response to one of the following questions.

1. With the anticipation of further declines in funding to support public health preparedness and response activities and programs, what areas would you suggest that we focus on to best utilize our resources to support state and local public health departments?
2. Please provide comment or perspectives on the 10-year strategic plan, specifically what interests you, what you would pay special attention to, and what issues you might have suggestions for addressing.
3. How might we advance and extramural research enterprise for preparedness systems improvement now that the Preparedness and Emergency Response Research Center (PERRC) funding has been discontinued?

T. Inglesby: During this section, we will answer one of the questions that Dr. Khan has posed to us. We will start with Ellen.

E. MacKenzie: I just finished the PERRC review, so I will answer Question 3. They need more evidence for best practice. They are a young field, and there is more work to be developed. I have two other points. It is imperative to develop the research capacity and develop investigators in the field to support them when funding goes away. There is no other funding that has a public health preparedness theme. If it continues to be more NIH-focused, we may lose the public health perspective. I came up with three thoughts of what to do for the PERRCs. The first one is not to give up. We felt they worked extremely well. They are developing research capacity and structure. CDC should figure out some way of continuing this. Get their products out there so that you will have return on investment for those products. If you had a smaller amount of money, focus that on individual research projects. Everybody is doing good work but not all the work is fantastic. Disperse according to individual projects, which require a well-crafted CDC agenda. Put a Request for Proposals out there targeted toward what you think is most important. That would be what I would like to see most of all, but if you have less money, keep the PERRC investigators connected. Develop a database for investigators, such as a website or a type of forum, to share ideas. Lastly, young investigator awards or dissertation grants can be valuable, but if you support the dissertations or young investigators and they do not have a place to go after funding, that can be discouraging. However, it will interest young people and get them engaged in bringing in multiple disciplines.

A. Khan: Ellen those are excellent points and novel.

L. Rowitz: To that same question, we have a certain paradigm as to how we do research, and we need new ways to create partnerships with universities to jointly do the research. Researchers are spread across the country. We need to find a way to work together or to encourage those partnerships, something like the NIH Centers for Excellence. You can also work within CDC to add preparedness questions into research throughout the agency. If CDC's Office for State, Tribal, Local and Territorial Support (OSTILTS) has an initiative, add a question regarding preparedness so that this office is not completely responsible, but can add dollars to another research initiative to get some answers. I agree with Ellen's suggestion to focus on a project-focused model versus several models. There was the thought to move from a 5-year to a 3-year model, and 3 years is not enough time. I like Ellen's idea on new investigators. They can add preparedness beyond their startup grant.

M. Butel: What about industry?

E. MacKenzie: It was brought up, and we said to look for funding in private as well as public sectors. It is not easy but it seems like a very natural thing to do.

D. Sosin: The CDC Foundation is very targeted and it is hard to do general public health research. They want specific things. We have to think about the questions.

L. Rowitz: I think there was hope that the Meta Leadership Initiative might be a way, but it has not been researched enough.

P. Quinlisk: To the first question, after a decision to get states and locals prepared for doing emergency response, the money is now decreasing. It is concerning that the time and effort we spent to get ready will be undermined by the lack of resources. We have used preparedness for everyday issues as well as terrorist events, and it would be a waste to let that system fall apart due to lack of funding.

M. Gilchrist: From the laboratory side, with regard to Question 1, we do not take advantage of models that have worked. A possible review topic would be to look at what is working and how can we adopt that in other places. Perhaps reduce some functioning that hasn't work and put more funding behind what is working and promote those.

T. Inglesby: Do you think those things are discoverable through current processes?

M. Gilchrist: Put out queries for things that are working and check to see if they are working well.

A. Khan: Do you have any ideas of what is working well in the labs? Any best practices that we should encourage?

M. Gilchrist: Things that are not working are linkages between hospital labs and state health labs. They are weak in some cases and in other cases very good. People in state laboratories that come from a hospital lab do better with the linkages than a career person in a state lab who does not have a clue of what happens in the hospital laboratory.

K. Smith: Not being much of an optimist regarding funding, I am looking at when there is no money. We are not doing well with what we are learning in events large or small. In particular, I do not think we are doing well at using some of the newer evaluation techniques to help us learn what it was about the response that was effective. If you cannot do that, you can not translate it effectively to others. Translating these will make good training activities. We cannot lose the increased nimbleness of the CDC and its ability to respond, particularly from a leadership perspective. If we look at severe acute respiratory syndrome (SARS) and the advice given, that has improved radically. Connecting those other parts of the CDC branch into preparedness should not be lost. I am a huge proponent of after action reports, but if that is all we have, we will be limited by having the actual staff to write it up.

D. Arnold: These are all great comments. I am focus on defining what a public health professional is and what this track will look like. We are losing workforce. We have to look at alignment within a community based setting. The community must feel like they are engaged and be involved in the process. This will get the ground swell that we need. Building resiliency is a positive chip for CDC to use to push these things forward. And lastly do not forget IT, IT, IT.

H. Palacio: I want to build on to a comment John made yesterday. We spent a lot of time talking about metrics, but if we want to measure that for preparedness, we need to focus more broadly on those accountability measures. Not only is funding reduced in public health preparedness (PHP), but a lot of our capacities lie outside of the PHP funded realm. That area is also being eroded just as equally if not faster. If my immunization is going down, then I do not have nurses to use in a pandemic flu. Policymakers need to hear these stories with data to support it. We need to think about a more broad view of what the capabilities are to show what we have and what risk we are at, as we erode from multiple pressure points.

D. Burke: What can you do with less money? CDC has an extraordinary amount of data that is buried or needs to be digitized, for example. The Obama Administration is very interested in making data available and developing new applications for analysis of health data. You have an enormous resource but it is relatively unused. You can open analytic data for things like chronic disease or automobile accidents, and this would require little money at all. Take advantage of what you have and make those data available. There are a good many folks interested in milling through that stuff.

H. Palacio: Be flexible. Let jurisdictions fill in their gaps of what they feel is all-hazards preparedness.

D. Arnold: In the state, it would be good to have a cost savings table so that we start with better tools and people are not reinventing the wheel.

M. Butel: Regarding Question 1, look at proficiency and continuity of the professionals themselves. It is key to the quality training that goes with that, evaluation of those exercises, and efficiency of the people. Address ways to establish continuity of links between activities at the individual levels.

S. Phillip: This crosses Questions 1 and 3. We talked about how modeling can help us be more efficient and what tools should we be investing in. As we look at a scare resource environment we need to provide whatever tools or resources to help people make these difficult decisions. Modeling helps you anticipate resource needs. Are there tools that you can be investing in with the academic community to do some of this predictive modeling? How can we use modeling to help determine where the easy wins are to get the biggest return for your investment?

T. Inglesby: Did anyone do Question 2?

J. Lumpkin: I think there could be more precise mention of the EMS system and all those components to serve as a foundation for some of the preparedness work. The National Association of EMS Directors and EMS Physicians would be thrilled to volunteer their time and efforts to get engaged. We are seeing a worst case scenario at the state and local level in regards to cuts, and there is uncertainty around there. What does public health looks like if a jurisdiction decides they do not need a health department anymore? How

do we ensure that preparedness continues to play a role in jurisdictions as we get further into the future? Arnold Damon mentioned IT. The world is different now. We have social media. We mentioned the social network the military is using. The Robert Wood Johnson foundation is doing some efforts there, and we can use these networks to share experiences. In New Mexico, they use a method called ECHO. It is a video-conference technology used to do case-based learning. Think about those ideas to create a cadre of experts, who may not come to CDC but can be actively engaged. Lastly around practicing, look at and pull those experts from other sections of public health in to help them expand their cadre of individuals involved in these efforts.

J. Muckstadt: I think I am the only member of this board who learned about public health by attending these meetings. I cannot disagree with what I have heard. My view would be that we use data properly to evaluate consequences. What is the return on investment? Companies only ask for assistance when they are in trouble. A lot of the comments related to what goes on in the field cannot be overstated. What would happen if all these people disperse and how do you contact them and make sure people will respond? The use of models is important to get people to understand the problems that might arise. It helps do the analysis for the model. Interpreting things in different ways will greatly assist you on what will be effective.

D. Burke: You talked about how to learn from existing events and commented on not having time to collect that information during an event but that is the time to collect information. In the last mile issue, there are lessons learned that need to be collected and studied. It does not have to be studied by those in the response right then but maybe an external group. Find some way to address problems beforehand and it could be a cheap way to get information.

J. Muckstadt: I do not think it is cheap but it is imperative. It is not cheap to build infrastructure that will stand up to the test of providing information that will inform. After 9/11, we were trying to build a secure cellular system in New York so they can cover every area of the city with multiple towers. That was a $500 million project.

D. Burke: I understand that but we know there will be behavioral changes, and things that happen during an event that need to be collected for future lessons learned.

J. Lumpkin: That is an important point. What we have been doing is formative evaluation where we get the evaluators together at the beginning to formulate those things. It would be nice to have a designated person who just collects that action before and during to get enhanced information.

L. Rowitz: Jack, you reminded me of the best kept secret of research. We have to find the real cost of doing a specific type of research project. We put high cost figures on some of the research, so our universities demand that we apply for the top amount to do that research. There needs to be some thought

about what it takes to do that study because we may waste money on doing some of this stuff.

J. Muckstadt: That is a good point, and it is something that NIH brought up briefly as well. We have to involve several universities and using students to work as summer interns for may be a year so you can accurately get the projects you want in the most cost effective way. There is not going to be money do things with a business-as-usual approach.

D. Arnold: I agree with what John was saying about the issue of having someone to record things. I think that is essential and it is a great idea. We keep talking in terms of money but public health is not here to save money but to prevent pain and premature death. That is a hard thing to put a number to. It is also getting community back to functioning so you do not have ongoing loss. We need to be able to capture that and figure out how to avert downstream loss by not restoring. What will be the cost paid by not addressing these issues?

T. Inglesby: In Question 2, I think the objectives in the strategy are at a very high level versus objectives that you know when you have achieved them. You will have a hard time getting someone to disagree with these, but you will have a harder time displaying failure. We need to be explicit about what the goals are in the OPHPR Program. Provide CDC expert training to all state and local health departments. That should be a strategic objective with money attached to it. Right now with what you have, it is hard to fund that, so illustrate the consequence of not doing or providing funding for that effort.

Updates from Liaison Representatives (10 min each)

Association of Public Health Laboratories (APHL)
Mary Gilchrist, PhD

We warned of the possibility of a leading edge. For the first person who comes down with an illness, if we could get the one organism out of that person and have an identification before other people come in, we would have the advantage. We know hospital laboratories were using equipment that could not identify some of the things we needed to collect. We had a lot of people who were spending a lot of time floundering with organisms and discarding the organism before we could identify it. We started a program to encourage folks to send their organism to the state, and the state would try to rule out pathogens of interest. If they could not, they would send it to CDC.

The planning worked reasonably well with old fashion efforts that have been replaced with PCR. Those labs are still interfacing with bigger labs and continue sorting through unknown organisms and trying to rule out bioterrorism pathogens. In most cases, it is not a bioterrorism pathogen or a plague.

T. Inglesby: Do you publish the work you discover?

I am sure I can get my hands on that.

To have a comprehensive view of what is going on, you need to have collaboration with the state laboratories to see the whole menu of things that are happening. You can then look for what is not being done. This could be a component of the review. Maybe at our next meeting we could have a one-hour review of what laboratories are doing and their stumbling blocks. People are trying to prove they are worthy of the funding they are getting. Perhaps the APHL can do surveys that are anonymous to get information on products that are working and not working. We could offer a much more comprehensive discussion.

Association of Schools of Public Health (ASPH)

Dr. James Curran was not able to attend.

Association of State and Territorial Health Officials (ASTHO)
Damon Arnold, MD, MPH

We have been working on several projects and have a lot of agendas. There is obesity, tobacco cessation, and accidents to name a few. One of my sister agencies had 22 to 100 percent cuts in some of its essential areas and cuts in its funding streams. There is a concern that we are seeing an increase in the number of events happening due to global warming, and we are seeing those during diminishing funding. We want to make sure we are covered. We are doing an analysis to see where we are going and how to sustain what we are doing.

With the local health departments, we are working on standardization of skills. This goes back to the idea of loss of institutional knowledge. People have lost a lot of their workforce, and it hinders an appropriate response. We are continuing to work with CDC on those issues and with other partners.

We also are trying to come up to speed on IT, particularly with the new Medicare requirements and getting the proper infrastructure in place to meet that need. Some states are stepping back hoping this will go away, which is not a correct response. We are addressing this collectively to make sure we are going in the right direction.

We also wanted to start using public health shields or badges that provides recognition in the field. People know what your role is and that you are valuable to whatever event you are responding to.

There are issues with the environment side of things. We have heard debates of eliminating the EPA. We have many people coming forward with farming issues and challenging some of the ordinances. I will forward to you a briefing to give you more insight on that subject.

Council of State and Territorial Epidemiologists (CSTE)
Patricia Quinlisk, MD, MPH

We have similar barriers with funding like others, loss of staff, etc. The Preparedness Grant is important to us. Whatever we can do to help support those who have power over the budget to let them know how critical this is to states we are willing to do. We will continue to work with you on the importance of that grant.

The CEFOs are also very critical to states that have no mountains or shorelines which are not effective in drawing talent. CEFOs need to be more available to states that have less funding but are in desperate need for a CEFO's expertise. We need that program to expand into those less economically plush states.

The Emergency Operations Center has been a big boom to response and general communications. The emergency centers have helped on a number of levels, and we use them for communications during non-emergencies. We would like to continue to support that system.

While we talk about being prepared for big events, remember preparedness for non-events. We find ourselves trying to make sure that there is not an event that we need to respond to. As an example, we had a child die of an unknown type of encephalitis. We had never had that in Iowa and people were considering going public with this information because we had flooding going on. We were able to send that sample to CDC to determine that there was not anything going on. This is just as important to know.

National Association of County & City Health Officials (NACCHO)
Karen Smith, MD, MPH

I want to give OPHPR kudos on their work. They really started reaching out to state and local level health departments, and it is key to get to those on the ground during a response. There are about 2800 health departments and many employees, so bringing the local health perspective is a very complex process. We have to choose representatives for workgroups to address these issues. We have been working with the DSLR framework and doing outreach to local health departments to explain the shift in the workforce.

We have also been working with grant alignment. We were able to provide input in the OPHPR Strategic Plan and worked with the PERRC review. We are actively planning ways to continue the work of turning what we are learning about the science into tools that can be disseminated and adapted for jurisdictions. We are also working with federal partners on the implementation of the National Health Security Strategy.

The last mile is an area we work on. We are also developing a curriculum. We did a preparedness summit this year that broke records and is a part of our focus to distribute CDC information. There was unprecedented tribal participation there as well. Having those folks at the table is critical.

Another contribution is our survey of preparedness at the local level to capture the contribution on that echelon. This helps to inform congress. There is a lot of monitory contribution of local government funds and capturing that is challenging. We are refining our instruments to determine what to feed to CDC.

Two challenging areas are emphasis on recovery and resilience and the metrics with that. We have a metrics workgroup that is taking a look at that. I have not heard any one yet give a good definition of what that is and what it looks like, but that is important. Another big area is vulnerable populations. As grants redefine how we identify those groups, it makes it hard to put activities together that address those issues.

National Indian Health Board (NIHB)

Ms. Stacey Bohlen was not able to attend.

D. Arnold: In the State Health Improvement Plan, we have this as five priorities in nine different levels. The state health improvement plan is a good way to see where these states are moving. Looking at the programs we have lets you look at best practices, evaluate those, and informs you on if those practices are working or not. It is a snapshot of what is going on in the states.

T. Inglesby: Jim and Stacy were not able to attend but will give updates for future meetings.

Brief Recap on the Fiscal Allocation Process

Bill Digioia, MBA, Director, Financial Resources Office, OPHPR

T. Inglesby: We will spent 5 minutes on the fiscal allocation process and get a snapshot of that.

B. Digioia: In 2011, $3.4 million became available for new products. From 2011 to 2015, there is $6.6 million to give out for the competitive PHEP process. The most important thing to note is the PHEP is our major area that we can use money from.

T. Inglesby: The list of projects provides a basic sense of the projects but does it really total to the total amount? Some of these are ending at '11 and this is today's project list and then new ones in '12?

B. Digioia: Yes, we had 27 more submitted.

L. Rowitz: Why is '14 so low?

D. Sosin: Some projects are not coming due at that time. Some of these are multi-year projects.

T. Inglesby: At the next meeting is it possible for us to better understand what is in each of these boxes?

B. Digioia: There is $139 million for core funding and out of that $6.6 million is discretionary.

A. Khan: Discretionary has been filled over the last decade. This includes the LRN and the EOC.

B. Digioia: We need to look at the core projects. Should they still be core or take some of those away to give more to discretionary projects?

A. Khan: Next year we have a $14 million cuts in core funding, so we have to figure a way to cut programs in those areas.

D. Burke: Do you distinguish between research and operations?

D. Sosin: There is development in those core funds as well.

D. Burke: We do have to record out research to OMB and they want to know how much we spend on research

D. Sosin: But that is a narrow focus with the OMB.

A. Khan: The program has to make hard decisions. But these continued cuts make it more than narrowing. When you split these funds between states and territories, it is not a lot of money.

Program Response to BSC Recommendations for the Division of Select Agents and Toxins (DSAT) External Peer Review

Rob Weyant, PhD, Director, DSAT, OPHPR

Thank you for the opportunity to briefly address the Board on our progress and the recommendations made by the Homeland Security Institute in regards to Division of Select Agents and Toxins. I wanted to give you a brief description on what we do, our work related to the Homeland Security Institute and then some current issues of interest that we are working through.

Our mission is to regulate the possession, use and transfer of select agents and toxins and the importation of etiological agents, hosts, and vectors of human disease to protect public health in the United States. Our vision is to be the preeminent resource for the safety and security of biological agents and toxins. We have about 115 staff members with 50% of those being FTEs. We have a budget of $15 million and we are located in Roybal, Building 20, 4th floor.

Programs cover 49 HHS and overlap agents or toxins. There are approximately 325 entities registered with DSAT. We issue about 2,000 import permits. About 11,000 individuals are currently authorized to work with select agents in CDC-registered entities. We conduct roughly 200 inspections and process approximately 1,500 registration amendments per year.

We are highly integrated with two other agencies and departments in the federal government. CDC is responsible for public health. We have partners at APHIS from the USDA. About 95% of these program relationships overlap with those in the Department of Agriculture. The third partner is the Department of Justice. CJIS does the security risk assessments or background screening. They report to us or the individuals in the Department of Agriculture, and then we determine whether to authorize agents.

There were two concerns that arose from the October 2007 Hearing. There was a feeling that a lot of money was being spent on new laboratories being constructed but there was little coordination. The work was going so fast that the federal government could not oversee all the safety and security. The CDC is committed to improve oversight by reviewing additional documents prior to site visits and do more in-depth interviews of workers. They would also conduct an external review of the DSAT, provide better outreach, and create a Trans Federal Taskforce Study.

The Homeland Security Institute reviewed our program and came up with 29 recommendations that we divided into the follow categories:

- Mission and Strategic Plan
- Records Management
- Process Documentation
- Inspections
- Training
- Staffing
- Guidance and Outreach

The BSC deliberated and voted to approve the recommendations in August 14, 2009.

Rather than go through all 29 recommendations, I thought I might address what we have done in terms of each of the broad categories and then talk about ones that we are still working on. You have been provided in your reading materials the actual 29 recommendations broken down.

In regards to mission and strategic plan, we now have Annual DSAT Leadership Retreats. These are facilitated by OPHPR's Office of Policy, Planning and Evaluation for the development and review of activities as they relate to our mission and vision, initiatives and objectives, and resource utilization. We monitor on a monthly basis the goals and objectives to assess where we are.

We had two periods of time where we got a significant influx of resources, 2002-2003 as a result of the Bioterrorism Act. These periods extended the responsibilities of the Select Agent Program. The second time was in 2009. OPHPR has seen fit to support the enhancements proposed.

Our original structure has evolved. It used to be a very flat and simple organization. That structure limited us in our ability to recruit SMEs, establish critical outreach and public programs, and provide more effective oversight of our regulatory activities. We now have a Biosafety team to provide oversight and inspect the laboratory functions. Each one is different and complex. There are tremendous advances going on in science and our office is helping us to keep up with those advances.

We have done other enhancements since 2009:

- Select Agent Inspections/Compliance Activities
    - Reduced Inspection Window from 3 yr to 1.5 yr
    - Reduced Security Risk Assessment Window from 5 yr to 3 yr
    - Unannounced Inspection Program
    - Performance Improvement Program
- Policy/Regulatory Enhancements
    - Proposed Rules to Strengthen Import Permit and Select Agent Programs
- Outreach Programs
    - National Workshop Series
    - Guidance Documents

We did an audit of our electronic system. Over a 2½ year period we performed the NSAR Database Audit. We conducted a detailed review of the historical information contained in the

National Select Agent Registry (NSAR) database, including over 600,000 data fields. Discrepancies determined to be errors were corrected and subjected to a peer review to ensure accuracy. The final error rate was approximately 5%.

We handle a lot of records, so we have done a lot of changes in this area to improve efficiency. We want to move from paper-based to electronic and get our staff more comfortable with an electronic environment. Doing this also helps us save money. We have several Records Management Initiatives:

- Inventoried all records and expanded storage space to streamline records storage
- Established entity guidance documents to reduce incoming document volume
- Assessed document lifecycles to eliminate duplicative processes
- Leveraged unused NSAR capabilities to enhance records management practices
- Formed permanent workgroups to document and communicate DSAT processes
- Enhanced DSAT scanning and printing technologies to decrease costs and increase production
- Increased the use of email attached documents to decrease the volume hard copy records
- Centralized and streamlined internal document routing to increase speed and accuracy
- Implemented scanning to decrease hard copy record storage and increase document availability
- Trained file managers to use NSAR to reduce reliance on hard copy records
- Leveraged DSAT's records retention schedule to speed the transfer of documents to National Archives and Records Administration (NARA) site

To improve the NSAR database, we hired two full-time employees to manage a team of contractors to conduct and complete an alternative analysis for the NSAR database. We also executed an initiative to begin the Enterprise Performance Life Cycle (EPLC) process for a potential new IT solution with anticipated implementation by 2014.

In terms of documentation enhancements, we had procedures but nothing was finalized. Since 2009, we have established the Standard Operating Procedure (SOP) Development and Review Process. This process provides dedicated administrative support and leadership oversight through the DSAT Deputy Director. We got to try out one of our SOPs in the Washington, DC area because there was a hurricane and an earthquake in the same week. APHIS had to shut down, but we were able to monitor the select agents registered with APHIS until they were able to resume business.

To our inspection process, we added an Operations Branch Chief position to make sure we are uniform from inspector to inspector and inspection team to inspection team. We have enhanced the inspector resources by converting all inspector positions from contract to federal, increasing the number of inspectors, and developing a comprehensive inspector training program. This has resulted in:

- More inspections (1.5 year average vs. 3 year average)
- Risk-based Inspection Schedule
- Unannounced Inspections
- Joint inspections with other stakeholders
- Plan for Import Permit Inspections

With regard to training, there has been:

- Development of DSAT Science Office
  - Associate Director for Science
  - Dedicated training staff
- Internal training Enhancements
  - Uniform comprehensive initial training for all DSAT inspectors
  - Ongoing training
    - Biweekly inspector sessions
    - Utilization of Individual Learning Accounts for Specialized Training
- External Training Enhancements
  - CDC/APHIS/FBI National Training Workshop
  - Inspection "Playbook" for Stakeholder Agencies
  - Responsible Official Training (in development)

In a couple of weeks we will have our first cohort of onsite training with our external people in Atlanta.

There are 37 new FTE positions with new subject matter expert positions available as Operations Branch Chief (Select Agent Inspections), Security Expert, Emergency Response Expert, Associate Director for Science, Dedicated Training positions, Dedicated Policy position, and IT Project Manager.

We have published a series of eight guidance documents since 2009. They can be viewed at www.selectagents.gov. The topics covered are around security and synthetic genomics. We have a booth when we go to national meetings and have participated in the American Society for Microbiology, BIO, and American Biological Safety Association meetings.

We have completed 24 of the recommendations:

- Completed Recommendations N=24
- DSAT's Mission and Vision Statement (Recommendation #1)
- Strategic Planning (Recommendations #2 & 30(a))
- IT design document (Recommendation #4)
- Information Control Policies (Recommendation #7)
- Process Documentation (Recommendations #10, 11(a, b, c, e, f, g, & h), 12, 13, 14, 15, & 18(a, b, c,& e))
- Inspections (Recommendations #16 & #20)
- Training (Recommendations #17, #22, #24, & #25)
- Biosecurity (Recommendation #19)
- Financial/budget assessment (Recommendation #21)
- Staffing (Recommendations #26 & #27)
- Guidance and Outreach (Recommendations #28(a, b, & d) & #29(b))

The ongoing recommendations are:

- Improvement to NSAR database (Recommendations #3, #5, #6, #30(b), (c), & (d))
  - Anticipated completion date of January 2014
- Update current APHIS/CDC forms and obtain input from regulated community (Recommendations #8 & #9)
  - Reviewed by DSAT and Animal and Plant Health Inspection Service (APHIS) as part of a 3-year cycle (current forms expire on 12/31/11)

  - DSAT and APHIS held "Joint Application Design" sessions at APHIS/CDC workshops and published notices in the Federal Register
  - Anticipated completion date of December 2011
- Create biosecurity risk assessment guidance and procedure (Recommendations #11(d), #18(d), & #28(c))
  - DSAT, in collaboration with APHIS, has developed an in-house security risk assessment tool (Sabercat)
  - Developing a process in which a test group of select agent entities can compare Sabercat with the biosecurity risk assessment tool developed by Sandia Laboratories (BIORam)
  - Anticipated completion date of November 2012
- Training metrics (Recommendation #23)
  - DSAT developed learning objectives for the comprehensive training program which will be used to update our internal training program
  - Anticipated completion date of September 2012
- Outreach initiative (Recommendation #29(a))
  - Process of developing a Responsible Official/Alternate Responsible Official training program
  - Anticipated completion date of spring 2012

Discussion and Recommendations

Thomas Inglesby, MD, Chair, OPHPR BSC

T. Inglesby: Any questions about program or response to recommendations?

M. Butel: What do you see as a risk with the NSAR database?

B. Weyant: IT security -- we are going to have to think through how to make a secure portal. Another potential risk is budget. Cuts will push back our implementation schedule. We have a system that is up and running now, but heaven forbid if something happens.

T. Inglesby: How many inspections are conducted a year?

B. Weyant: About 200. Some years are busier than others. We want to work with some entities to inspect them more frequently. We use a point system to determine how frequently we want to visit.

T. Inglesby: How many do not pass inspection?

R. Weyant: We need a system that better grades inspection. We are not there yet. We have put 3 to 5 percent on a performance improvement program. It is a private matter between us and the entity. Once they have been notified, that information is then subject to the state as well.

J. Lumpkin: What relationship do you have with the National Science Advisory Board?

R. Weyant: I am an Ex Officio member to provide technical information that has contributed to two of their reports.

D. Burke: Is this data comparable to other countries, and is there any official network?

R. Weyant: There is not an official network, but we have had meetings with those who do work that is similar, including those in other countries. We have compared notes. We did one in Singapore, and I hope it grows into something more official. It affords more contact with the key players that can bear fruit.

T. Inglesby: Who are the other members?

R. Weyant: Canada, United Kingdom, Germany, and Brazil to name a few. I can provide you with a list of the attendees.

T. Inglesby: That would be useful.

R. Weyant: We may have some legal obligations to allow people to submit information through other methods, but our statutory regulations do not prescribe how they must do that. We are working on our first manuscript. It is been an interesting story. Prior to 2007, we received very few incident reports. Since then we have seen a 10-point increase on the number of those reports that come our way. In terms of making information available, the specific information about the incident is sensitive, and we feel a due diligence to protect that. But we can share some global level things.

T. Inglesby: The FAA has information regarding near misses. From what I understand if you report your near misses you are protected, but if you sit on it, then you can get in trouble. They find it valuable for continuing improvement. What formal process do they have for near misses?

R. Weyant: We are almost there but not quite there, and I do not know if we can go all the way to that point. We encourage reporting. We take a positive and helpful approach to addressing reports, but if it is the result of longstanding compliance issues, we have an obligation to report that.

T. Inglesby: That is far enough but requiring people to report misses and having someone to look at that is essential.

R. Weyant: That is what we are essentially trying to achieve. Even if you are not sure if someone got exposed, advise us, and we will work with you on that.

T. Inglesby: Can you talk us through an inspection?

R. Weyant: It depends. If it is a large federal institution we will send a team of 10 to 12 people and they will spend 2 weeks going laboratory to laboratory. A letter is sent to let them know we are coming 90 days before. Our inspectors walk through the lab areas to assess safety and security, interview random laboratorians to see if they understand safety plans, review inventory, and

make sure access control are done properly. The inspectors have a closeout conference to make them aware of serious concerns. The inspectors return to Atlanta, do a report, and submit the report in a timely manner.

D. Arnold: Have there been any select agent human infections?

R. Weyant: Yes, a hand full.

T. Inglesby: No deaths?

R. Weyant: No deaths

T. Inglesby: Can you say what those were?

R. Weyant: We do have those in an annual report to Congress, and we can provide those.

D. Arnold: How is the transfer of substances and standards handled with different countries?

R. Weyant: If an individual wants to import a select agent, they have to be registered, and we process based on their select agent. For non-select agents, you have to apply for a permit.

Vote on Summary Determinations

Thomas Inglesby, MD, Chair, OPHPR BSC

J. Lumpkin: Recommendations 3, 5, 6, 8, 9, 11, 18, 23, 28, 29, and 30 would be indicated for additional report until they are completed.

J. Muckstadt: I second.

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

J. Lumpkin: I move to approve the remaining recommendations that have been addressed.

J. Muckstadt: Second.

T. Inglesby: All in favor say Aye.

Board: Aye [All agree]

T. Inglesby: Oppose?

Board: [None]

T. Inglesby: Abstain?

Board: [None]

T. Inglesby: Any question? Let's see the rest that you have.

Rob Weyant, PhD, Director, DSAT, OPHPR

HHS was tasked with making a select agent list. The Select Agent Program was a transport program until the Amerithrax Attack in 2001. The FBI Amerithrax Report generated additional concerns about threats to people working in the laboratories. To that, the EO 13486 was released to have a survey conducted for federal oversight of this work. That was followed up with EO 13546. There were a number of expert panels convened to look at personnel reliability, and we have taken recommendations from those to use for the proposed new regulations. The reviews utilized were:

- *Enhancing Personnel Reliability among Individuals with Access to Select Agents.* National Science Advisory Board on Biosecurity
- *Responsible Research with Biological Select Agents and Toxins.* National Research Council
- *Dept. of Defense Biological Safety and Security Program.* Defense Science Board
- *Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories.* GAO-08-1092
- *World At Risk.* WMD Commission
- Executive Order13486 Working Group on Strengthening Biosecurity in the U.S.

From EO 13546, we were tasked with a list of duties:

- Tiered/Reduced List of Biological Select Agents and Toxins (BSAT)
- Federal Expert Security Advisory Panel (FESAP)
    - Recommendations on strengthening personal reliability of BSAT workers
    - Recommendations on strengthening physical security at BSAT facilities
- Streamlined Agency/Department BSAT Policies
- Coordinated Inspections
- Better Information Sharing between Federal Agencies

The FESAP also made recommendations to our program on November 2, 2010. They suggested that we look at tiering or a reduction of the BSAT list. They also asked us to look at personnel reliability, physical security, and cybersecurity.

T. Inglesby: Will roles be divided between different agencies?

R. Weyant: HHS and USDA will maintain those roles. It was suggested we get input, and we have done so, but regulation is still with HHS and USDA. We look at physical security for now and we may be developing some others.

P. Quinlisk: What agents are being taking off to reduce the risk?

R. Weyant: I am not at liberty to release the list. We are required every two years to review the list.

A. Khan: There will be no surprises.

T. Inglesby: Is there a separate DoD process for how they think about security?

R. Weyant: The select agent regulations relates to all laboratories. The DoD has policies, like a lot of agencies that go above and beyond select agent regulations.

D. Arnold: Do you have authorities to do inspections in other agencies?

R. Weyant: Any laboratory that has select agents including DoD we have authority to do inspections.

T. Inglesby: So when you hear that a laboratory is working under onerous conditions, DSAT provides the foundation for guidance. But they can go beyond what you are doing.

R. Weyant: Right. We have done a lot to coordinate our work, and we try to show up at the same time to reduce the amount of time a laboratory undergoes inspections.

D. Sosin: So DSAT determines the specific regulations but it does not keep others from setting more stringent regulations. These are the minimum.

R. Weyant: Yes, and Section 8B does call for other government agencies to bring their policies into alignment with the final rule.

T. Inglesby: Any other questions? Well this has been helpful. It is time for public comments.

Public Comment Period (Day 2)

There were no public comments.

Closing Remarks (Action Items and Future Agenda)

Thomas Inglesby, MD, Chair, OPHPR BSC

Thank you CDC for all your work and your time. I want to thank everyone for your participation and I look forward to talking to you in November and in our April meeting.

RADM Ali S. Khan, MD, MPH, Director, OPHPR

Thank you everyone for your time and I think this meeting went quite well. We will talk more about separate issues and how we are moving forward.

Barbara Ellis, PhD, Designated Federal Official, Associate Director for Science, OPHPR

Hopefully our paths will cross in other activities, but I want to thank you all. It is been a phenomenal amount of work to get through in the last couple of days. Thank you for all your efforts and your service to CDC. We are grateful for your tremendous work.

Adjourn/Certification

With no further business raised or discussion posed, Dr. Inglesby officially adjourned the OPHPR BSC meeting.

I hereby certify that to the best of my knowledge, the foregoing minutes of the September 14-15, 2011 OPHPR BSC meeting are accurate and complete:

_____
Date

_____
Dr. Thomas Inglesby, MD
OPHPR BSC Chair

OPHPR BSC Membership Roster

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CEO and Director
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Executive Secretary

Barbara A. Ellis, Ph.D.
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Bashor	Mark	OPHPR
Burel	Greg	OPHPR
Carbone	Eric	OPHPR
Chiv	Carol	OPHPR
Cioffi	Joan	OPHPR
Crawford	Sara	OPHPR
De La Cerda	Hilda (Pamela)	OPHPR
Frace	Mike	NCEZID
Gangadharan	Denise	OPHPR/DSAT
Garza	Roberto	OPHPR
Geibe	Jesse	OPHPR (DoD liaison)
Gorman	Sue	OPHPR
Groseclose	Saw	OSELS
Horan	John	OPHPR
Jones	Terrance	OPHPR
Kennedy	Dave	DEO
Kokor	Valerie	OPHPR
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Weyant	Robbin	OPHPR/DSAT
Williams-Johnson	Mildred	OPHPR
Wooster	Mark	DEO
Public Attendees		
None		